Managing the Demand for Elective Orthopaedic Surgery: Challenges, Strategies, and Results in New Zealand.

A Thesis for the Degree MD (Otago)

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Personal contribution

All research requires teamwork and collaboration. I believe that collaborators and co-workers should be recognized and take a part in the authorship of the paper. As a general principle if a student or registrar has collected data and written a first draft they have been given as first author, even if I extensively revised the manuscript, and I will be second or final and corresponding author. Co-authors who have performed roles such as statistical or radiographic analysis are usually given as second or third authors. If a registrar has collected data and given a verbal presentation but I have written the manuscript from first draft I will usually be first author.

I have been the lead author on 24 papers and Principal Investigator and/or Corresponding Author on a further 9 papers. In 4 papers (4.1, 5.2, 5.7, 6.3) I have been a co-investigator and had significant involvement in some or all of: the original idea, study design, clinical supervision, data analysis, writing, review and revision of the final manuscript.

Paper 5.3 *Cardiopulmonary exercise testing. A comparison of different exercise modalities in patients with hip and knee osteoarthritis* will be used by Brendon Roxburgh as part of his PhD submission. I am a co-supervisor of his PhD (20%) and have been involved in the conception and design of the work, patient recruitment, interpretation of data, drafting of the manuscript and subsequent revisions. Brendon Roxburgh and Holly Campbell performed the experimental work, Brendon wrote the initial manuscript and Dr Kate Thomas was principal investigator, primary supervisor, and corresponding author.

No publication has been used for a previous degree.

Abstract

Managing the demand for elective orthopaedic surgery: Challenges, strategies, and results in New Zealand.

Introduction. There is increasing demand for orthopaedic surgery and public health systems, in NZ and around the world, are struggling to manage. In New Zealand emphasis has been placed on fairness, timeliness, and giving the patient certainty which has led to the development of prioritisation systems and explicit rationing. This thesis of publications is based on research undertaken in Dunedin over the past 20 years. During this period there has been an increasing mismatch between demand and capacity for orthopaedic surgery in general, and hip and knee arthroplasty in particular. A variety of strategies have been employed to try to improve access to elective orthopaedic surgery.

Methods

The thesis is divided into chapters examining various aspects of the problem.

1) Drivers for the increasing demand for elective orthopaedic surgery, and competing demands for resource including acutes.
2) Carpal tunnel syndrome. What we can achieve with good access.
3) Prevention. Neonatal screening for developmental hip dysplasia
4) Alternatives to surgery. Improving non-operative management and comparing results with surgery.
5) Scoring, prioritisation and consequences of rationing with respect to total joint replacement (TJR).
6) Improving the perioperative management of patients.
7) Results of surgical treatment. Getting it right first time and improving the outcomes of surgery

Results.

There is not equity of publicly funded provision of total joint replacement (TJR) across the country. The demand for surgery in Otago has been quantified and is increasing. There is little that can be done to prevent the demand. However, screening for Developmental Dysplasia of Hip (DDH) can reduce late presenting hip dislocation and its long-term

sequelae. Alternative models of care have been effective in managing CTS. There is a high incidence of CTS in the elderly with good results from surgery.

Non-operative management through a dedicated physiotherapy led clinic can be helpful for patients with hip and knee osteoarthritis (OA). Patients with knee OA are more likely to benefit than those with hip OA. However, the functional results at long term follow up are poorer than those who have undergone surgery. The scoring tools used to prioritise TJR have been validated but they are not discriminatory around the threshold. Declining surgery and returning patients to their General practitioner (GP) achieves little especially for patients with hip OA who are more likely to deteriorate. The long-term effects of rationing and under provision leads to worsening severity of patients qualifying for public surgery. Gains in health related quality of life are related to severity at presentation but those most severely affected may not get as good a final result. Hip and knee replacement are highly cost-effective procedures by three years.

Enhanced recovery protocols have resulted in improved efficiency and shorter patient stays despite older and sicker patients. Excellent long term results have been achieved following Total Hip Replacement (THR) with up to 95% revision free survival at 18 to 20 years which match or surpass published international results. Choice of implant fixation is important with hybrid fixation in THR having the lowest risk of revision surgery.

Conclusions Elective orthopaedic interventions such as carpal tunnel decompression and total joint replacement are highly effective. There is a limited role for non-operative treatment in end stage hip and knee OA. Scoring and rationing may be effective up to a point. There have been gains in efficiency despite older and sicker patients presenting for surgery. Despite these efforts, there remains a significant mismatch between demand and capacity and there is a clear need for increased investment in elective orthopaedic surgery.

Introduction

There is increasing demand for orthopaedic surgery and public health systems in New Zealand (NZ) and around the world are struggling to manage. Waiting lists for elective orthopaedic surgery are a feature of most publicly funded healthcare systems. They can stretch to several years and have typically been targeted by increasing short term funding to do additional operating lists. This puts pressures on hospitals and staff and is not usually a sustainable solution. In contrast in New Zealand government policy has tried to limit wait times and placed the emphasis on clarity for the patient, timeliness of surgery and fairness. If resources are limited there is an explicit requirement that they are allocated on the basis of clinical priority and ability to benefit. [1]

To understand the current environment in NZ it is helpful to understand a number of key changes made over the last 25 years. In 1996 Ministry of Health policy changed and a booking and prioritization system was introduced, in effect "abolishing" waiting lists.[2] In the new system patients were required to be seen within 6 months for a First Specialist Assessment (FSA) and if advised surgery were to have their surgery within 6 months of the certainty decision. Compliance was monitored via the Elective Surgery Performance Indicators (ESPIs). ESPI 2 relates to the wait for outpatient appointments and ESPI 5 to the wait for surgery. The 6-month wait was progressively reduced to 4 months where it now stands. District Health Boards (DHBs) are required to prioritise patients so that those with the greatest need are given certainty for either an FSA or surgery. This led to the development of scoring and prioritization systems. These are termed the Clinical Priority Access Criteria (CPAC). They initially took the form of tables with a priority of 1 - 5 for conditions, each of which had a prescribed score. Subsequently other scoring systems have been developed which are discussed during the course of this thesis. To remain compliant with ESPIs it was possible for a DHB to decline to see the patient or decline surgery if they were unable to guarantee it within the 4-month period.

The second change was the introduction of Accident Compensation Corporation (ACC) Elective Services contracts in 1997. [3] This transferred the purchase of elective services for patients who had a claim accepted by the Accident Compensation Corporation from the Regional Health Authorities to ACC. This resulted in a separate stream for procedures such as knee arthroscopy, rotator cuff repairs etc. This put less pressure on public hospital lists for post- traumatic elective procedures as most are done in the private sector. As a result the bulk of most public hospitals' work is lower limb arthroplasty for degenerative osteoarthritis and trauma.

When I commenced work as a consultant orthopaedic surgeon in 2001 there were problems with unmet need for joint replacement surgery in NZ but access in Dunedin was among the best in the country. In 2003 the New Zealand Orthopaedic Association published a paper 'The ageing of New Zealand' that outlined the impact of the ageing population on musculo-skeletal conditions including hip fractures and joint replacement. [4] It detailed the number of hip replacements that would be required and the implications for orthopaedic funding and training. This resulted in the Ministry of Health funding the 'Orthopaedic Initiative' which ran from 2004 to 2008, with a requirement to double the number of elective hip and

knee joint replacements performed in public hospitals.[5] This was successful at improving access across the country but had less impact in Otago. [6]
Funding for the District Health Boards was reviewed under a population based funding formula (PBFF). [7] The details of this formula lack clarity but include weightings for age, gender, ethnicity, and deprivation. It also includes adjusters for unmet need, rurality and overseas patients. [8] Under PBFF and the associated Future Funding Pathway the share of income to the Otago District Health Board has slowly decreased over the last 20 years. Well-publicized budget deficits have put pressure on Dunedin Hospital and access to elective orthopaedic surgery has significantly declined. In 2010 the Otago and Southland DHBs combined to become the Southern DHB (SDHB). This has had little effect on orthopaedics as both base hospitals (Dunedin and Southland) have remained independent in operational terms. However, it has become harder to extract data at the hospital level due to all reporting being combined.

I have maintained a public hospital clinical practice for the last 19 years and was Clinical Leader/Director for 10 years. My clinical practice is predominantly hip and knee arthroplasty but also general orthopaedics and trauma. When I took up the post of Clinical Leader of the Orthopaedic Department in 2009 there were significant issues with access to both orthopaedic surgery and orthopaedic outpatient appointments. Approximately a third of patients referred for an orthopaedic FSA were being declined and a third or more of patients that were recommended for elective surgery and in particular total joint replacement were not qualifying. When I somewhat naïvely wrote to the Chairman of the DHB advising him of this, I received the facetious reply "There is only so much money, if you need more then tell me who I should take it from". This led to my first paper *Quantifying the demand for hip and knee replacement in Otago, New Zealand* as I sought to use academic papers to prove the need for change and publicise the issues.[6]

After several years of lobbying a large project was developed called "The Orthopaedic Patient Pathway Programme" (OPP). The Ministry of Health, under the Elective Services Productivity and Workforce Programme (ESPWP), funded this with the aim of producing "an end to end transformational change" of the "orthopaedic patient journey" in Dunedin. The projects and key performance indicators (KPIs) set by the Ministry of Health implied that:

1) improved non-operative management of patients with hip and knee OA could reduce the demand for surgery
2) too many patients were being seen for follow up appointments so there was inadequate capacity for FSA
3) surgeons were not prioritizing patients consistently and "soft scoring" was driving the demand
4) patients were being cancelled on the day of surgery leading to inefficient list utilization
5) inadequate discharge planning was leading to longer lengths of stay
6) non-medical resource could do many of the jobs that would free up surgeons' time.

I was sceptical about some of these assumptions and the need or the ability of the OPP to generate transformational change but felt that it was an opportunity to improve the service. I believed that the system was working well with most of the issues due to a true mismatch between demand and capacity and problems such as bed block and over-load of acute

admissions. I was designated Clinical Champion and, in addition, a Programme Coordinator and a Facilitator were appointed. The goals of the projects within the programme included the development of the Joint Clinic to improve access and non-operative care of patients with hip and knee osteoarthritis, streamlining of both inpatient and outpatient processes including the introduction of enhanced recovery after surgery (ERAS) techniques, and the use of non-clinical resource to help prioritise referrals and patients for surgery. The programme ran from 2012 to 2014 and led to many of the publications in this thesis.

As surgeons I believe we are in the best position to assess the effects of operative, non-operative and management solutions with real world experience. We need to question dogma, received wisdom, published results and the next new idea, often imported from overseas, promoted by Ministry of Health or hospital management. The thesis does this and explores the strategies that we have employed to try to improve elective surgery provision in Otago. It includes 37 papers covering research done over a 20-year period and has a New Zealand perspective due to the environment in which we work. However the problems and solutions are not unique to New Zealand and will be relevant to other healthcare systems under financial stress.

Chapter 1 quantifies the demand for joint replacement in Otago, looks at drivers for the increasing demand including age and obesity, the equity of access to joint replacement across NZ and the problems with the balance between acute and elective surgery including the effect of overseas tourists requiring orthopaedic admission.

Chapter 2 uses carpal tunnel decompression as an example of a high volume, low cost, low complexity procedure with similar challenges that is being managed effectively.

Chapter 3 reports the results of our programme to prevent hip disease through neonatal hip screening.

Chapter 4 looks at alternatives to surgery and improving non-operative management. The first section reports on the development, implementation, early and long-term results of the Joint Clinic, a physiotherapist and nurse led clinic for patients with hip and knee OA. The second part compares outcomes of surgery and non-operative treatment with respect to acute Achilles tendon rupture.

Chapter 5 reports on surgical prioritisation, scoring tools and their validation, a new referral prioritization tool and the consequences of the use of these tools to ration services in Otago.

Chapter 6 includes papers on improving the perioperative management of patients. It covers care pathways introduced 20 years ago and enhanced recovery after surgery (ERAS) results from more recently. It also includes papers on the use of intraoperative fluoroscopy to reduce complications of surgery.

Chapter 7 looks at the results of surgery. By “getting it right first time” complications and the need for repeat surgery can be reduced. This will save theatre time and costs. Appropriate implant choice can reduce the revision burden but as hip and knee replacement

is typically successful this requires large long term studies. This chapter includes cohort studies on the outcomes of THR and Total Knee Replacement (TKR) that include patient reported functional results and long-term results and large local series focusing on revision rates with different implants and modes of fixation at long-term follow up. Finally it includes some papers reporting on uncommon complications and the ensuing problems, need for revision surgery and costs.

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Chapter 1

Drivers for the increasing demand for elective orthopaedic surgery, and competing demands for resource.

The increasing demand for elective orthopaedic surgery has been driven mainly by the ageing population and the increasing incidence of obesity. In Otago we have also seen the impact of a reduction in Ministry of Health funding under population based funding. In '*Quantifying the demand for hip and knee replacement in Otago, New Zealand'* I first quantified the unmet demand for joint replacement and explored the causes. I concluded that the main reasons were an increased proportion of the population aged over 55 years and a backlog of cases due to under-provision in previous years. The Otago DHB had missed an opportunity under the orthopaedic initiative to use "ring-fenced" funding. This was primarily due to a reluctance to out-source cases privately despite having inadequate public hospital capacity.

In '*Equity of publicly-funded hip and knee replacement surgery in New Zealand: Results of a national observational study'* we reported significant differences in access to joint replacement across New Zealand. Despite increasing numbers of procedures being performed the rate of publicly funded joint replacement surgery was barely keeping up with population increases. Larger DHBs had poorer age and ethnicity standardised rates than smaller ones.

We have also looked at the effect of overseas tourists on local services. Our region includes the tourist hot spots of Queenstown and Wanaka. There is an overseas adjuster in the PBFF but it is not clear how this applied and whether it has kept pace with changes in tourist numbers. The first paper '*Non-resident orthopaedic admissions to Dunedin Hospital: 1997-2004'* was prompted by changes in ACC legislation that meant that all tourists were covered for accidental injury when in NZ. The implication of this was that any tourist with an acute injury requiring admission was treated for free and could not use their insurance. Our follow up paper '*Non-resident orthopaedic admissions to Southern DHB 1997-2016: Changes over a 20 year period'* highlighted that the increasing numbers of tourists in our area was costing Southern DHB a disproportionate amount of their revenue as well as occupying beds and theatre space.

Finally in '*The projected burden of knee osteoarthritis in New Zealand: healthcare expenditure and total joint provision'* we respond to a paper on the effect of obesity and its implications for demand for knee replacement and highlight the mismatch between theoretical modelling and the real world and the resultant implications for policy makers.

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Quantifying the demand for hip and knee replacement in Otago, New Zealand

David Gwynne-Jones

Abstract

Aim The purpose of this study is to quantify the current demand in Otago for hip and knee replacement.

Methods Hospital databases and the New Zealand Joint Registry were used to calculate the intervention rate for primary total hip (THR) or knee (TKR) replacement between February 2010 and February 2012. All patients meeting the clinical threshold but waiting for surgery were also recorded over the same period.

Results The intervention rate for THR and TKR in NZ in 2011 was 33.0/10000 while in Otago it has varied from 30.7 to 42.6 over the last 5 years. This is at or above the national average based on population share. Over a 2-year period the numbers reaching the clinical threshold and waiting for primary joint replacement surgery rose from 247 to 347 patients, while 1496 primary elective joints replacements were performed. The current demand for primary THR and TKR is 798 per year (41.7/10000 per year). The unmet demand is 73 cases per year.

Conclusion The increased demand in Otago compared to the NZ average is due to greater numbers of people over the age of 55 years and the backlog of patients due to under provision relative to demand in previous years.

Osteoarthritis is a common condition affecting about 15% of adult New Zealanders.[1] It is typically a disease of older age and hence the prevalence is likely to increase further as the population ages.

Hip and knee replacement are highly successful operations for symptomatic osteoarthritis. In response to increasing demand the Ministry of Health introduced the joint initiative in 2004 with the aim of increasing the rate of publicly funded major joint replacements. In Otago the agreed volumes were an increase of 160 cases from a base contract of 315 to a new target of 475 major joints.

It is government policy that there should be nationally consistent access to surgery. Prioritisation tools such as the Clinical Priority Access Criteria (CPAC) score and the Hip and Knee prioritisation tool developed by the Orthopaedic Working Group of the National Waiting Times Project are used to varying degrees across the country. Currently the target national standardised intervention rate (SIR) for publicly funded major joint replacement (primary, bilateral or revision hip or knee replacement) is 21.0/ 10000 population per year.

In 2009, following the end of the joint initiative, the minimum number of joints required to be performed in Otago was reduced from 475 to 425 in order to match the SIR. It appears that the clinical need for surgery is significantly greater than this.

A DHB must not offer certainty of surgery to a patient if they are unable to perform the surgery within 5 months (6 months until June 2012) (Elective Surgery Performance Indicator (ESPI) 5). Patients not meeting this "financial threshold" may be placed on Active Review (AR) if their condition is likely to deteriorate and meet the threshold within the foreseeable future, or they are returned to their General Practitioner (GP) for ongoing care and monitoring.

In Otago the financial threshold has risen to an unacceptably high level in order to maintain ESPI compliance. This has led to an increasing number of significantly disabled patients now not qualifying for surgery in the public sector.

The purpose of this study is to quantify the current incidence of hip and knee arthritis in Otago that is severe enough to justify primary hip or knee replacement and compare it with local and national intervention rates in both public and private sectors.

Methods

All patients undergoing hip and knee replacement in NZ are registered in the NZ joint registry (NZJR) for which there is 98% compliance.[2] Figures for primary and revision total hip (THR) and total knee replacement (TKR) and unicompartmental knee replacement (UKR) were obtained for calendar years 2007–2011.

Numbers performed at Dunedin Public Hospital (DPH) and Mercy Hospital, Dunedin were also obtained from the NJR and cross referenced with numbers of cases performed at the hospitals from prospectively gathered figures. Bilateral cases are counted as two separate procedures in the NJR, but as one procedure to calculate the SIR for major joint replacement. UKRs were included in the figures for TKR. THRs for acute hip fractures were excluded.

The Public sector financial year runs from 1 July to 30 June. DPH figures were available by month from July 2006 to June 2012. Cases performed at a private hospital under contract from the DHB were classified as publicly funded. ACC funded cases were classified separately or included in private figures. Patients were placed on the public waiting list if they had failed medical management and were judged by a consultant orthopaedic surgeon to be a suitable candidate for THR or TKR.

The hip and knee replacement tool developed by the Orthopaedic Working Group of the National Waiting Times Project (Appendix 1) was used to score the patient and an Oxford hip or knee score (OHKS)[3] given to the patient to complete. For the last 2 years the threshold for certainty has been 79 points or higher and active review over 62 points. Patients falling below the threshold for active review are classified as Clinical Benefit (CB). These patients are returned to their GP for ongoing care. Surgery is rarely advised if the score is less than 50 points.

Total numbers of patients in each category have been recorded over the past 3 years. The two years 2010 and 2011 were analysed to determine the current level of demand based on intervention rates and changes in total waiting list numbers.

An audit of all patients seen for FSA at DPH with a hip or knee problem between February and August 2012 was performed. The outcome of the consultation, (wait list, discharge, further investigation etc), CPAC score and Oxford score were recorded and final decision regarding certainty, active review or return to GP was noted. All patients on active review are sent a questionnaire including an OHKS. For this study the OHKS was scored from 0-48 with 0 the worst and 48 the best possible score.[3]

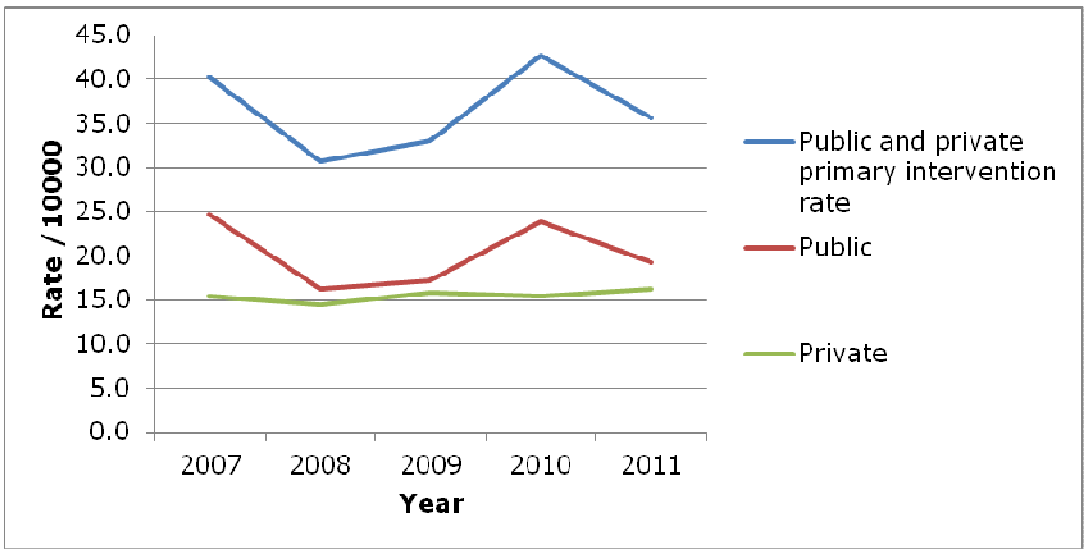
Population figures (191,361) for the Otago region (excluding Queenstown) were based on the latest estimates from Southern DHB funding and planning department. The national population figure was taken as 4,271,223.

The 2006 Census figures with 5-year age bands were used to compare Otago to New Zealand.[4] Comparative raw intervention rates for England and Wales and Australia were calculated from their respective joint registries.[5,6]

Results

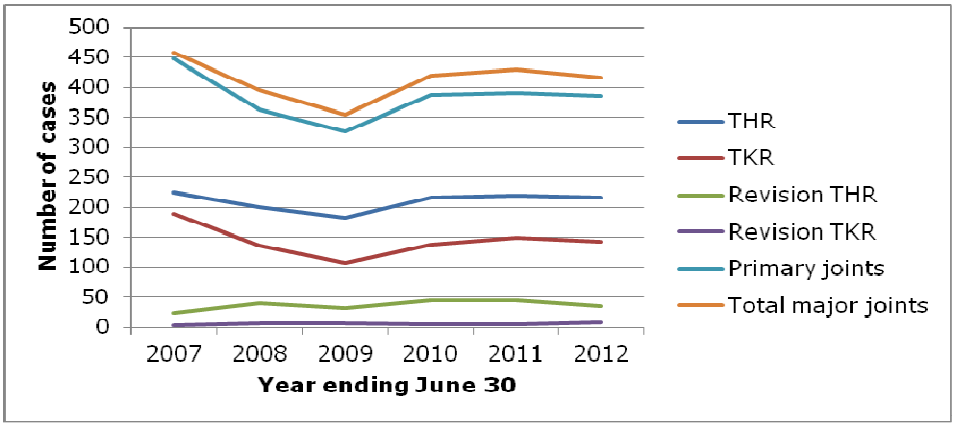
The intervention rate for primary THR or TKR in New Zealand has risen from 28.9/10000 in 2005 to 33.0/10000 in 2011. In Otago the rate has varied from 29.2 in 2005 to 42.6 /10000 in 2010 with the variation chiefly occurring in the public sector (Figure 1).

Figure 1 Intervention rates per 10,000 population per year for primary elective THR, TKR in Otago calendar years 2007–2011



The breakdown of major joint replacements in the public sector is shown in Figure 2.

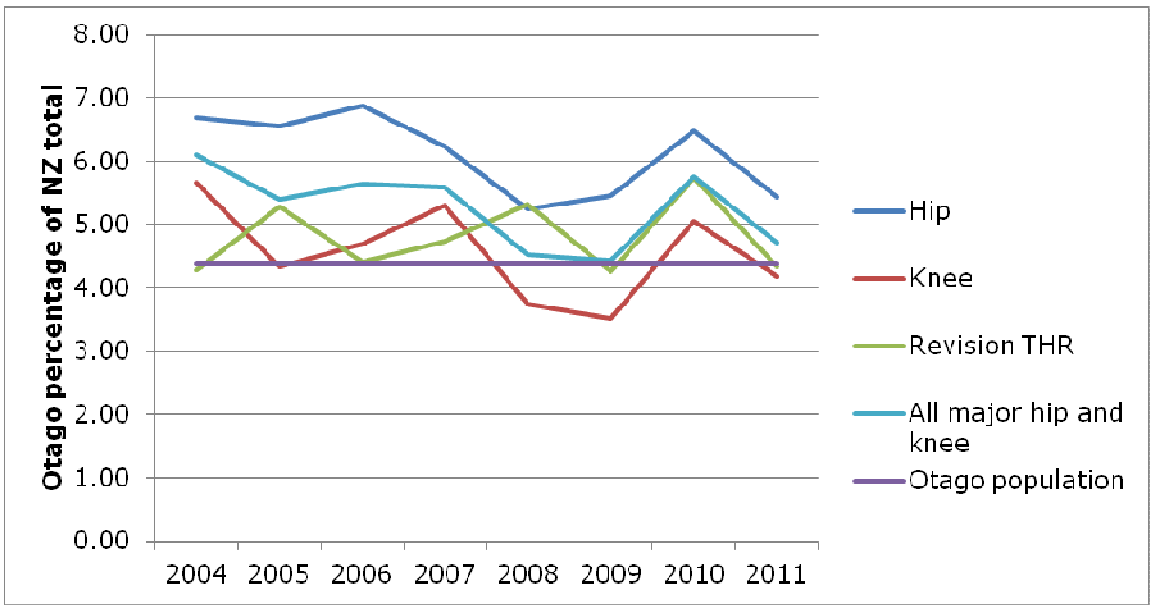
Figure 2. DHB-funded elective major joint replacements (financial years ending 30 June 2007–2012)



Fewer than the target volume of 475 joints were performed in years ending June 2008 and 2009 due to problems with dropped lists due to acute cases, and lack of beds, theatre and anaesthetic resource. The target volume was reduced to 425 joints for year ending June 2010. Over the last 3 years there has been a shortfall of only nine joints.

Otago comprises approximately 4.5% of the NZ population. Since 2007 Otago has provided major joint replacements at or above the national average based on its population share. (Figure 3). This is mainly due to high rates of primary hip replacement with the rate of primary knee replacements below the population share for three of the past 4 years.

Figure 3. Percentage of joint replacements performed in Otago compared with New Zealand total (public and private combined)



From 1 February 2010 to 1 February 2012 the number of patients on the public waiting list for primary hip and knee replacement surgery rose by 100 from 247 to 347 patients. (Table 1) During this time 4389 referrals were received at DPH, 2558 (58%) were seen and 1183 referrals (27%) were returned. These included 234 patients referred with hip or knee arthritis.

In the same period a total of 1496 primary elective joints were performed in Otago (mean 748 per year): 827 (55.2%) were funded by the DHB, 53 (3.6%) by ACC and 616 (41.2%) in private (insurance or self-funding). (Table 2)

Table 1. Waiting list at Dunedin Public Hospital

Status	February 2010	February 2012	August 2012
Certainty	72	127	126
Active Review	66	114	162
Clinical Benefit	109	106	106
Total wait list	247	347	394

Table 2. Details of primary joint replacements performed in Otago 2010–2012

	Feb 2010–Feb 2012	%	Per year	Intervention rate/10000 per year
Joints performed	1496		748	39.1
Public	827	55.2	414	21.6
Private	616	41.2	308	16.1
ACC	53	3.6	27	1.4
Change in total waiting	+100		+50	2.6
Total demand	1596		798	41.7

Therefore the current minimum demand for primary hip and knee replacement in Otago is 798 per year. This equates to an intervention rate of 41.7/10000 per year.

Currently there is funding for approximately 390 primary hip or knee replacements or 20.4/10000 per year by the DHB for the Otago region. This assumes no change in the number of revisions or bilateral procedures performed. An additional 335 are performed in private or under ACC.

This gives a shortfall of 73 primary joints per year. If these were to be funded by the DHB then the contracted volume would need to rise by 17% to 498 major joint replacements per year.

Over the 6-month period February to August 2012 the total public wait list for primary hip or knee replacement increased by a further 47 patients despite performing 209 procedures (Table 1). During this period a total of 225 patients were seen at DPH out-patients with a hip or knee problem. 155 (69%) were listed for primary TKR or THR of whom 96% had a Oxford score of 20 or less, 74% less than 15 and 37% less than 10 points.

124 (80%) scored over 70 points on the CPAC score, while 76 (49%) scored 79 points or more. In total 81 patients (52%) were given certainty, 61 patients (39%) were placed on active review and 13 (8%) were classified as clinical benefit and returned to their GP.

On average over the last 12 months, 82% of patients, initially classified as active review, have moved to certainty.

Discussion

It is difficult to estimate demand for primary hip and knee replacement. In this study we have collected data on all patients meeting the clinical threshold for THR or TKR whether they were placed on the certainty or active review list or were returned to their GP with advice.

Our end point therefore is based on orthopaedic assessment, radiographs and patient reported scores in a patient suitable for surgery. In order to accurately compare our figures with other DHBs similar data need to be collected.

Using intervention rates allows comparison between countries but assumes no limit on access. In 2009 Germany had the highest rate of hip and knee replacement at 50.1/10000.[7] The rates for Australia and England and Wales are 30.6 and 30.5/10000.[5,6] In New Zealand the combined public and private intervention rate in 2011 was 33.0/10000.

The intervention rate for primary THR and TKR in Otago (public and private combined) has been at or higher than the national average for many years. Despite this current demand exceeds capacity by 7–10% per annum.

We made a number of assumptions in calculating the demand for primary joint replacement in Otago. In the private sector these include that there is no limit on private hospital capacity, there is no net flow of private patients in or out of the province and the number insured and the number prepared to self-fund remain constant. These are reasonable assumptions but may underestimate the future demand for publicly funded surgery.

There is good access to primary healthcare in Otago and this may be a cause for the high number of referrals made requesting an FSA. The limited access to FSA is likely to underestimate the potential demand. During the 2 year study period 234 referrals of patients with hip or knee arthritis were returned. At least some of these are likely to have reached the clinical threshold for joint replacement. However, many of these may have subsequently been re-referred and will appear on the waiting list figures.

There may be a number of reasons for the increased demand. In the public sector raw intervention rates are corrected to the standardised rate by a formula that includes age, gender, rural location and deprivation. Revision procedures are also counted in the standardised intervention rate. A higher number of revisions will reduce the number of primary procedures that can be performed. Nationally the revision burden (percentage of revisions to primaries) is approximately 13% for hips and 8% for knees. In Otago the rates are 12.3% and 4.3%.[2]

The proportion of patients with health insurance or able to afford private healthcare may influence demand in the public sector. However, high rates of private provision may not be associated with better access to publicly funded surgery.[8] Otago does not appear to have a smaller than average private sector.

In 2010/11, DHBs had widely differing rates for the percentage of joint replacements performed in a private hospital (range 9% to 73%). [2] These figures include public cases contracted out to private hospitals so reflect the use of out-sourcing as well as the private market.

Otago was on the median for the country with 44% of cases performed in a private hospital but during this time only 14 joint replacements were out-sourced. It has been reported that rural populations have a higher need for hip replacement[9,10] but not for knee replacement.[10] This may partially explain why there is a much higher rate of THR than TKR in Otago.

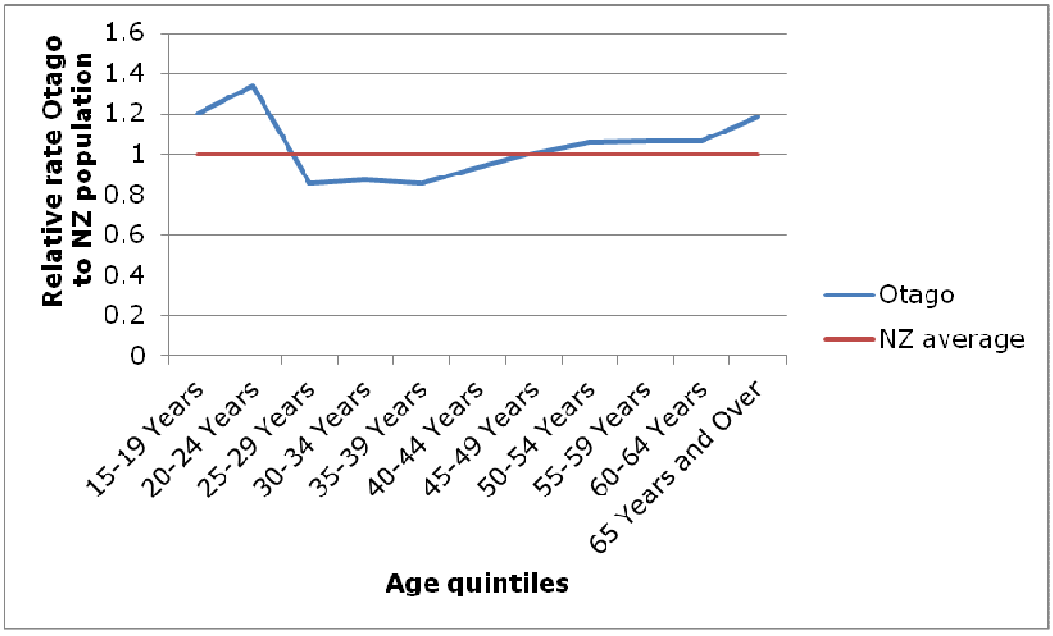
The local orthopaedic surgeons do not appear to be more likely to recommend joint replacement than average. In the audited 6-month period the Oxford scores of those patients wait-listed in public were less than 20 in 96%, less than 15 in 74% and less than 10 in 37%. In a large study from Scotland the average OHKS for patients undergoing THR or TKR was 18.3 and 18.7 respectively.[11]

Age is strongly associated with increasing demand for joint replacement. Eighty eight per cent of primary hip and knee replacements in NZ are performed in the over 55 age group.[2]

Despite having a large young student population there is a higher proportion of people for each 5-year age group over 50 years in Otago than the NZ average (Figure 3). The prevalence of people over 55 years relative to the NZ average is 1.13 and over 65 years is 1.18.

Adjusting the national intervention rate of 33.0/10000 to reflect this would result in an age adjusted rate of approximately 39/10000 pa which more closely matches our estimated demand. In the public sector an increase of 73 joints per year from 425 would equate to a 17% increase.

Figure 3. Proportion of Otago population in 5-year bands compared to New Zealand population (figures from 2006 Census)[4]



Another key determinant of demand is the backlog of patients awaiting surgery. In the public sector there has been a shortfall of nine patients over the last 3 years against the minimum target of 425 major joints. The target for years ending June 2008 and 2009 was 475 joints (315 base contract plus 160 joint initiative).

The Dunedin Public Hospital capacity was restricted at this time by a shortage of anaesthetists and beds. This resulted in a backlog of 210 joints against potential public funding. Only a limited number of cases (34) were outsourced to the private sector between April and November 2008.

If the volumes had not been reduced in 2010 and 475 joints (12% greater than NZ average to reflect the age of the Otago population) had been performed each year for the last 5 years then an additional 358 joint replacements could have been performed which would almost eliminate the current waiting list of 394 patients.

Anecdotally we hear that some DHBs have very similar problems to Otago while in others patients are qualifying for surgery with a lower score or less severe symptoms regardless of whether their DHB is over or under providing against the national average. Some DHBs have no patients on active review while others have more than recommended. This may reflect either implementation of policy, or possibly a lower financial threshold.

When the clinical priority criteria were introduced the two crucial issues were whether they would correctly and consistently prioritise patients according to symptoms and ability to benefit from surgery and whether the thresholds would be chosen so as not to leave patients with clear needs untreated.[12]

We believe that the scoring tools are useful but lose the ability to discriminate at higher scores. However it is clear that currently the financial threshold in Otago is too high and many patients with severe symptoms who would benefit from joint replacement are not qualifying for surgery.

In conclusion in Otago the current demand for primary hip and knee replacement is approximately 41.7/10000. Current funding from the DHB is for approximately 20.4/10000 with the private sector and ACC providing 17.5/100000.

There is an unmet demand of at least 73 cases per year or 3.8/10000. The two main reasons for this are the greater numbers of people over the age of 55 years in Otago and the backlog of patients due to under provision in previous years.

To address both the ongoing local demand and the backlog, there needs to be additional provision for joint replacement surgery by the DHB or the situation will continue to deteriorate.

The problem is unlikely to be isolated to Otago and similar data needs to be collected to allow direct comparison between other DHBs. Using standardised intervention rates to determine volumes will not necessarily result in equity of access across the country.

Competing interests: Nil.

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Appendix 1. Hip and knee prioritisation tool

Criterion	Category	Category Descriptions – Assign patient to highest scoring category that applies *(Patient must be on optimal medical therapy at time of rating)*	Points
Pain	1	No Pain	0
	2	Episodic activity-related pain	
		May use occasional analgesics	4
	3	Daily pain with weight-bearing activity	
		2-3 times/week pm use of simple analgesics/NSAIDs	10
	4	Pain which cannot be ignored with activity and at rest	
		Sleep disturbance 2-3 times / week due to pain	19
		Daily analgesics/NSAIDs	
	5	Dominates life and interferes with sleep every night	
		Pain poorly controlled by analgesics	27
Personal Functional Limitation DUE to Hip or Knee Orthopaedic Condition	1	No Limitation	0
	2	**Minimal restriction of personal activities** e.g. trouble reaching toes	
		Walking stick used for longer walks	3
	3	**Moderate restriction of personal activities** e.g. requires help with socks/shoes	
		Requires help cutting toenails	9
		Use of walking stick indoors and outdoors	
	4	**Severe Restriction of personal activities** e.g. requires help with dressing or showering	18
		Consistently uses 2 crutches or wheelchair	
	1	No Limitation	0

Social Limitation DUE to Hip or Knee Orthopaedic Condition	2	**Mild Restriction** e.g. can't walk >1 hour	4
		Some limitation of leisure activity e.g. golf or tennis	
	3	**Moderate Restriction** e.g. can walk 15-60 mins	10
		Significant limitation of leisure activity	
		Can manage garden or bowls	
	4	**Severe Restriction** e.g. can't walk > 15 mins - slow	19
		Difficulty with steps or stairs	
		Severe limitation on leisure activity – can't maintain garden	
		Requires help with shopping	
		Some limitation to work	
	5	**Profound Restriction** e.g. confined to the property	23
		Shopping done by others	
		Requires meals or other domestic help	
		Can't work due to orthopaedic condition	
Potential to Benefit from Operation (for patient, dependents or community)	1	Small Improvement Likely – significant residual symptoms +/or functional limitation	0
	2	Moderate Improvement Likely – some residual symptoms +/or functional limitation	6
	3	Return to near normal likely – asymptomatic + full return of function	
Consequence of delay >6 months (for patient, dependents or community)	1	Little risk will deteriorate over next 6 months	0
	2	Considerable risk will deteriorate and result in increased disability during next 6 months	7
	3	Likely to progress to major complication during next 6 months with increased clinical costs, e.g. impending fracture or structural failure	24

Equity of publicly-funded hip and knee joint replacement surgery in New Zealand: results from a national observational study

Helen Harcombe, Gabrielle Davie, Sarah Derrett, Haxby Abbott, David Gwynne-Jones

ABSTRACT

AIM: This study examines equity in the provision of publicly-funded hip and knee total joint replacement (TJR) surgery in New Zealand between 2006 and 2013 to: 1) investigate national rates by demographic characteristics; 2) describe changes in national rates over time; and 3) compare rates of provision between District Health Boards (DHBs).

METHODS: Hospital discharge data for people aged 20 years or over who had at least one hip or knee TJR between 2006 and 2013 was obtained from the Ministry of Health's National Minimum Dataset.

RESULTS: Higher TJR rates were observed among those aged 75–84 years, females, those of Māori ethnicity, those not living in rural or main urban areas and those in the most deprived socio-economic groups. TJRs increased from 7,053 in 2006 to 8,429 in 2013, however the rate was highest in 2007. In 2012–13, age-ethnicity-standardised rates varied between DHBs from 196 to 419/100,000 person years, with larger DHBs having lower rates than smaller DHBs.

CONCLUSION: There was evidence of geographic inequity in TJR provision across New Zealand. Despite increased numbers of procedures, rates of publicly-funded TJR surgery are barely keeping up with population increases. Reasons behind differences in provision should be examined.

Healthcare budgets are constrained and there are perennial concerns about the potential mismatch between health-care need and the provision of publicly-funded services. Ageing populations[1] and technological advances[2] are increasing pressures on healthcare budgets and the prioritisation of healthcare services can be required.[3] One area that is likely to be affected by these pressures is total joint replacement (TJR) surgery. The most common reason for TJR surgery in New Zealand is osteoarthritis (OA)[4] that is not responding adequately to conservative treatment. OA has a high prevalence among older adults[5,6] with 29% of New Zealanders aged over 65 years diagnosed with this condition.[7] This is important to consider as, currently in New Zealand, those aged over 65 years comprise 14% of the population but this is predicted to increase to 27% in 2063.[8] Therefore, demand for TJR will likely increase substantially. In New Zealand, hip TJR surgery (including privately-funded procedures) has already increased between 1999 and 2013 by 75%; there was a corresponding 158% increase for knee TJR surgery.[6] However, despite these increases, concerns have been raised that the provision of these procedures may not be expanding sufficiently to keep up with increases in clinical need or population changes.[9]

Publicly-funded healthcare in New Zealand is provided by 20 District Health Boards (DHBs) "…responsible for providing or funding the provision of health services in their district."[10] In New Zealand, prioritisation scoring tools are used to determine access to publicly-funded TJR surgery. This should ensure equitable access across the

country. However, Derrett et al (2009)[11] found a lack of equity between DHBs in the provision of elective hip and knee TJR (2000 to 2005), and an analysis of New Zealand newspaper articles and Parliamentary questions from 2000–2006 found that "… access inequities remained a persistent theme…" (p.57).[12] Although there has been an increase in funding for TJR surgery in New Zealand in recent years it is not clear whether that has translated into increased rates of surgical provision. Additionally, any increases in provision of TJR should be equitable with regard to geographic and demographic determinants such as place of residence, age, sex, ethnicity and socioeconomic deprivation.[13] This paper examines publicly-funded elective hip and knee TJR surgery provision among DHBs in New Zealand from 2006–2013. The aims of this study are to:

1. describe changes in rates of publicly-funded hip and knee TJR surgery nationally between 2006 and 2013,
2. investigate whether national rates vary according to age, sex, ethnicity, small-area deprivation and rurality, and
3. determine whether the provision of publicly-funded hip and knee TJR surgery is equitable across DHBs in New Zealand.

Methods

This study examined New Zealand hospital discharge data for publicly-funded hip and knee TJR surgery from 2006–2013. Ethical approval for the study was received from the University of Otago Human Ethics Committee (Reference number D13/253). Relevant hospital discharge data was obtained from the Ministry of Health's National Minimum Dataset (NMDS).[14] The NMDS is a national collection containing publicly-funded hospital discharges and some privately-funded hospital discharges. Data was obtained for patients with at least one publicly-funded hip or knee TJR procedure who were discharged between 1 January 2006 and 31 December 2013. This time period was chosen as similar work on this topic[11] analysed data up until the end of 2005, and 2013 data was the latest available at the time this study commenced. The variables obtained from the NMDS included the International Classification of Diseases version 10 (ICD10) clinical code, age at discharge, sex, domicile code, ethnicity, type of admission, diagnosis type, event dates and the principal health service purchaser. As well as waiting list admissions, arranged admissions defined as "a planned admission where: the admission date is less than seven days after the date the decision was made by the specialist that the admission was necessary…"[14] were also included as these were likely to capture urgent sub-acute OA patients. Acute admissions and injury admissions (primary diagnosis code within ICD10 S00-T98)[15] were excluded as were those under 20 years of age at time of surgery and overseas residents. Hip and knee TJR surgeries were identified using the clinical codes in the 3rd edition of the Australian Modification of ICD10.[15] The specific procedures included were: total arthroplasty of hip, total arthroplasty of knee, total arthroplasty of knee with bone graft to femur or to tibia, total arthroplasty of knee with bone graft to femur and tibia and total replacement arthroplasty of patellofemoral joint of knee. Hemiarthroplasty of the knee was also included because indications for this are similar to TJR and their popularity may vary across the country. Revisions of hip and knee joint replacements were not included as the aim was to focus on primary procedures. Records with missing or historic domicile codes that could not be forward-mapped were excluded as these could not be analysed by DHB, area-level deprivation or rurality. Self-identified ethnicity data collected at the patient's health event was obtained from the NMDS. The recording of at least one ethnicity is mandatory, and two additional ethnic group codes may be recorded.[14] As the DHB-level denominator data was only available by 'prioritised ethnicity', this approach was used in our analyses with estimates obtained for Māori, Pacific, Asian and Other ethnicity groupings. Prioritisation follows a Statistics New Zealand (SNZ) algorithm with the end result being each person associated with only one ethnic group.[16] Māori ethnicity has the highest priority, meaning that people who identified as both Māori and any other ethnicities are classified as Māori. For example, those who identify as both Māori

and Pacific are classified as Māori. Pacific ethnicity is given the next highest priority with those who identify as Pacific and any other ethnicity (apart from Māori) being classified as Pacific.

The New Zealand Deprivation Index (NZDep2006) is a "…small-area index of relative socio-economic deprivation…"[17] (p.S7) derived from 2006 Census data. The NZDep scale runs from one (an area in the least deprived 10% of small areas) to 10 (in the 10% most deprived small areas). The 1:1 mapping between domicile codes available in the NMDS and Census area units used by SNZ enabled NZDep to be assigned to each TJR discharge record. Rurality was also derived from domicile codes by 1:1 mapping with SNZ's Census area units and SNZ's Urban/Rural Profile Classification.[18] The seven categories of the Urban/Rural profile were categorised for analysis as:

1. 'Main Urban' (described as being "… very large and centred on a city or main urban centre… minimum population of 30,000"),[18]
2. 'Other Urban' which consisted of 'Satellite Urban' ("defined as urban areas (other than main urban areas) where 20 percent or more of the usually resident employed population's workplace address is in a main urban area"[18] and 'Independent Urban' (defined as for Satellite Urban but <20 percent with a main urban area workplace), and
3. 'Rural' comprising the four rural profiles ('Rural Areas with a High Urban Influence,' 'Rural Areas with a Moderate Urban Influence,' 'Rural Areas with a Low Urban Influence' and 'Highly Remote Areas').

Denominator data were sourced from SNZ, and restricted to those aged 20 years and above. Annual resident population estimates by year, ethnicity, sex, age group and DHB region for 2006–2013 were calculated by SNZ. Usually resident population counts from the 2006 Census were used for calculations involving rurality and deprivation. In 2010 the Southern DHB was created from a merger of two DHBs (Otago and Southland); for this study we combined data from those DHBs and considered them as the Southern DHB throughout the period analysed. Crude rates per 100,000 person years (py) were calculated and presented alongside exact Poisson 95% Confidence Intervals (CIs). Age-standardised rates (ASRs) were calculated using direct standardisation and five-year age groups. Ten five-year age groups (<45, 45–49…80–84, 85+) were used for sex and ethnicity ASRs. Denominator data for deprivation and rurality ASRs was not available disaggregated by age for those over 65 years so these ASRs were calculated using age groups <45, 45–49, 50–54, 55–59, 60–64, 65+ years. Age- and ethnicity-standardised rates (AESRs) by DHBs were calculated in a similar way using four prioritised ethnic groups: Māori, Pacific, Asian and Other. Linear trends in rates were analysed using Poisson regression. Pitman's variance ratio test was used to compare the distribution of AESRs by DHB over time. Analyses were carried out using Stata/SE (version 13.1).[19]

Results

Of the 74,784 procedures obtained from the NMDS for people with at least one publicly-funded hip or knee TJR and a date of discharge between 2006 and 2013, 62,907 (84.1%) met the inclusion criteria. Figure 1 details the exclusions. Of these 62,907 publicly-funded primary hip or knee TJR procedures, 2% were bilateral joint replacements giving a total of 64,222 primary hip or knee joints replaced (Table 1).

Figure 1:

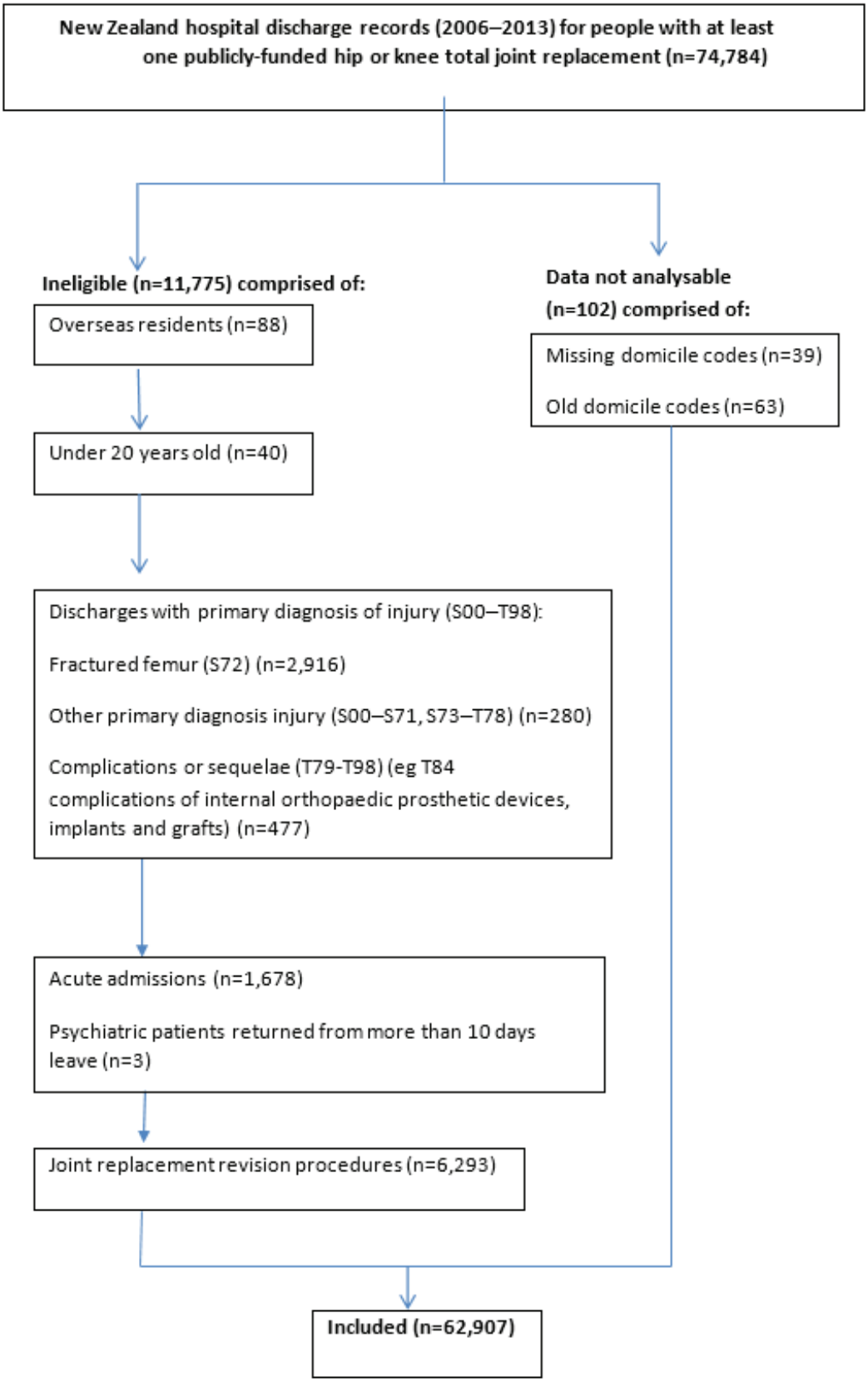

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Table 1: Publicly-funded primary total hip and knee joint replacement procedures in those aged 20 years and over, 2006–2013 by District Health Board (DHB).

District Health Board	Overall N	Bilateral %	Population*	Overall Crude Rate** (95% CI)	Ranking/20***
Auckland	3,472	1.8	330,660	131.3 (126.9, 135.7)	20
Bay of Plenty	4,373	1.9	149,663	365.2 (354.5, 376.2)	5
Canterbury	6,781	2.5	367,993	230.3 (224.9, 235.9)	16
Capital and Coast	3,001	5.4	211,259	177.6 (171.3, 184.0)	19
Counties Manukau	5,636	2.8	318,674	221.1 (215.3, 226.9)	17
Hawke's Bay	2,703	0.2	109,900	307.4 (296.0, 319.3)	11
Hutt Valley	1,918	5.3	100,735	238.0 (227.5, 248.9)	15
Lakes	1,827	1.4	71,043	321.5 (306.9, 336.6)	9
Mid Central	2,719	1.2	118,968	285.7 (275.1, 296.6)	12
Nelson Marlborough	3,015	2.4	102,653	367.1 (354.2, 380.5)	4
Northland	2,987	1.8	112,131	333.0 (321.2, 345.1)	8
South Canterbury	1,460	0.3	41,890	435.7 (413.6, 458.6)	3
Southern	4,734	2.7	222,008	266.5 (259.0, 274,2)	14
Tairawhiti	889	0.1	31,134	356.9 (333.8, 381.2)	7
Taranaki	2,013	1.3	79,248	317.5 (303.8, 331.7)	10
Waikato	5,757	1.4	256,493	280.6 (273.4, 287.9)	13
Wairarapa	866	0.9	29,839	362.8 (339.0, 387.8)	6
Waitemata	6,274	2.0	378,591	207.1 (202.1, 212.3)	18
West Coast	871	0.6	24,241	449.1 (419.8, 480.0)	1
Whanganui	1,611	0.8	45,012	447.4 (425.8, 469.8)	2
Total	**62,907**	**2.1**	**3,102,133**	**253.5 (251.5, 255.5)**	

*Population = Average DHB population for 2006–2013 of those aged 20 years and over.
** Rate/100,000 person years.
***Ranking is from highest to lowest overall crude rate for the 20 DHBs.

Table 2: Publicly-funded hip and knee total joint replacement procedures in New Zealand for those aged 20 years and over from 2006–2013 by year.

Discharge Year	Denominator	Number	Rate*	95% CI
2006	2982345	7,053	236.5	(231.0, 242.1)
2007	3015800	7,943	263.4	(257.6, 269.2)
2008	3046505	7,535	247.3	(241.8, 253.0)
2009	3083845	7,934	257.3	(251.7, 263.0)
2010	3124770	7,745	247.9	(242.4, 253.4)
2011	3158140	7,950	251.7	(246.2, 257.3)
2012	3185125	8,318	261.2	(255.6, 266.8)
2013	3220535	8,429	261.7	(256.2, 267.4)

*Rate/100,000 person years of those aged 20 years and over.

Nationally, the number of publicly-funded hip and knee TJR procedures increased by 19.5% from 7,053 in 2006 to 8,429 in 2013 (Table 2) while the rate increased by only 10.7%. The rate peaked in 2007 at 263/100,000 py before decreasing (2008–2011) and returning to 261 and 262/100,000 py in 2012 and 2013 respectively. Although there was a statistically significant increase in the rates from 2006 onwards (p-value <0.001), there is no evidence to suggest a linear change in the rates from 2007 onwards (p-value=0.2).

From 2006 to 2013 inclusive, the highest rate of publicly-funded hip and knee TJR procedures was for those aged 75–84 years at the time of surgery (1,063/100,000 py) followed by those aged 65–74 (907/100,000 py), with the lowest rate among those aged less than 55 years (45/100,000 py) (Table 3). ASRs were significantly higher for females (260/100,000 py) than for males (246/100,000 py).

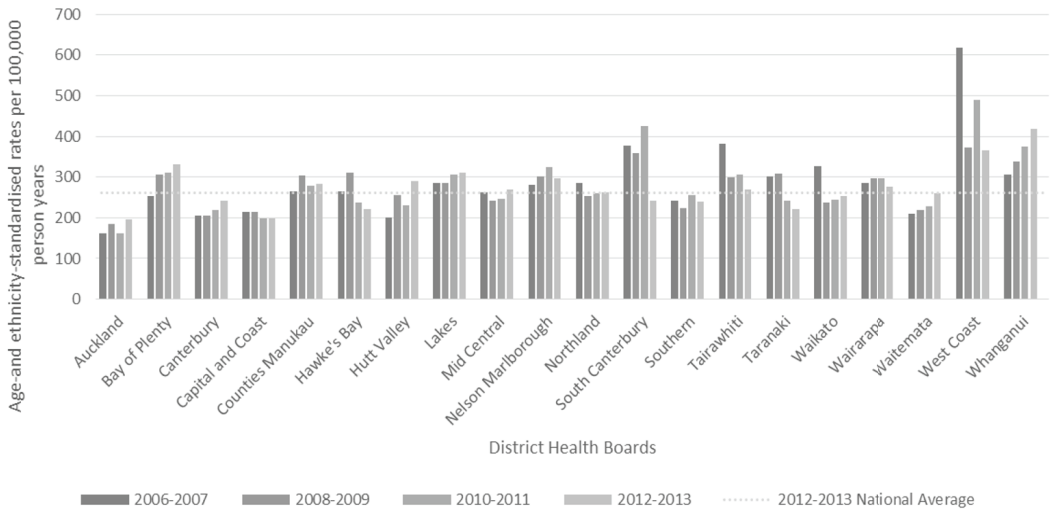
The crude TJR rate of 300/100,000 py was highest among those categorised as 'Other' ethnicity (ie those not identifying

Table 3: Publicly-funded primary hip and knee total joint replacement procedures for those aged 20 years and over for 2006–2013 by socio-demographic characteristics.

	Denominator*	N	Annual crude rate	(95% CI)**	ASR***	(95% CI)
Overall	**3,102,133**	**62,907**	**253.5**	**(251.5, 255.5)**	--	-- --
Age group (years)						
<55	2,066,311	7,405	44.8	(43.8, 45.8)	--	-- --
55–64	474,338	14,939	393.7	(387.4, 400.0)	--	-- --
65–74	311,123	22,581	907.2	(895.4, 919.2)	--	-- --
75–84	183,611	15,611	1062.8	(1046.2, 1080.0)	--	-- --
85+	66,751	2,371	444.0	(426.3, 462.2)	--	-- --
Sex						
Female	1,612,114	34,075	264.2	(261.4, 267.0)	259.7	(257.0, 262.5)
Male	1,490,019	28,832	241.9	(239.1, 244.7)	246.2	(243.4, 249.1)
Prioritised Ethnicity						
Māori	366,255	5,793	197.7	(192.7, 202.9)	303.1	(294.8, 311.5)
Pacific	158,319	1,809	142.8	(136.3, 149.6)	224.2	(213.4, 235.0)
Asian	327,923	1,259	48.0	(45.4, 50.7)	93.8	(88.2, 99.3)
Other****	2,249,636	54,046	300.3	(297.8, 302.9)	258.3	(256.1, 260.4)
Rurality						
Main Urban Area	2,037,012	40,003	245.5	(243.1, 247.9)	258.6	(256.1, 261.1)
Other Urban Area	399,417	14,672	459.2	(451.8, 466.7)	361.6	(355.7, 367.5)
Rural	362,802	8,230	283.6	(277.5, 289.8)	295.9	(289.4, 302.3)
NZDep						
1–3 (least deprived)	785,292	13,314	211.9	(208.3, 215.6)	219.6	(215.9, 223.4)
4–7	1,136,757	26,780	294.5	(291.0, 298.0)	279.9	(276.6, 283.3)
8–10 (most deprived)	877,113	22,806	325.0	(320.8, 329.3)	342.0	(337.6, 346.5)

*Uses 2006–2013 resident population estimates for all except Rurality and NZDep comparisons which use 2006 usually resident Census counts.
**Rate/100,000 person years (≥20 year- olds).
***Age-standardised rate.
****The numerator of those classified as 'other' ethnicity includes those with ethnicity recorded as 'Don't Know,' 'Refused to answer,' 'Response unidentifiable' or 'Not Stated' to align with denominator.

Figure 2: Age- and ethnicity-standardised rates of publicly-funded hip and knee total joint replacements per 100,000 person-years by District Health Board from 2006–2013.



as Māori, Pacific or Asian). Māori had the second highest crude rate (198/100,000 py). However, Māori had the highest ASR of procedures (303/100,000 py) followed by those of 'Other' and Pacific ethnicities (258 and 224/100,000 py respectively). Those of Asian ethnicity had a substantially lower ASR (94/100,000 py). Differences in crude and ASRs between prioritised ethnic groups were all statistically significant.

Rates were highest for people living in 'Other Urban Areas' (ie urban areas other than those classified as centred on a city or main urban centre) with a crude rate of 459/100,000 py and an ASR of 362/100,000 py). This ASR was significantly higher than the ASR for those in 'Rural' (296/100,000 py) and 'Main Urban Areas' (259/100,000 py).

There was a clear linear relationship between TJR procedure rates and socio-economic deprivation, with people that lived in the most deprived three deciles (deciles 8–10) having a significantly higher ASR (342/100,000 py) than those in deciles 4–7 (280/100,000 py) and similarly those who lived in the least deprived deciles (deciles 1–3) had a substantially lower ASR again (220/100,000 py).

Of the 20 DHBs, 10 had increases in their age- and ethnicity-standardised rate (AESR) of TJR procedures between the periods 2006–07 to 2012–13, one was unchanged and nine had a reduced rate (Figure 2). Of the eight largest DHBs by population, five had an increase in AESR: Bay of Plenty (31%), Auckland (22%), Waitemata (25%), Canterbury (19%) and Counties Manukau (7%). Southern's AESR remained unchanged and Capital Coast's and Waikato's fell by 7% and 22% respectively. In contrast, AESRs fell between the periods 2006–07 to 2012–13 in seven of the 12 smaller DHBs: West Coast, Wairarapa, Tairawhiti, South Canterbury, Taranaki, Hawke's Bay and Northland. However, in 2012–13, the six smallest DHBs by population (with the exception of South Canterbury) had AESRs higher than five of the six DHBs with the largest populations. Five of the eight largest DHBs (Auckland, Canterbury, Capital and Coast, Southern and Waikato) were below the New Zealand average of 261/100,000 py in 2012–13 as were three of the smallest DHBs (Hawkes Bay, Taranaki and South Canterbury). To assess whether the variation in AESRs by DHB had changed over time, the standard deviation of DHB's AESRs for 2006–07 was compared with that from the rates for 2012–13. Excluding one outlier (West Coast), there was no statistically significant difference over time (ratio of standard deviations 1.13, (95% CI 0.70, 1.82), p=0.6).

There were also variations by DHB for those in the most deprived deciles. For those in the most deprived three deciles, considering the eight years of the study combined, the ASRs varied from 236/100,000 py (Auckland) to 514/100,000 py (South Canterbury) (results not shown). Again, the smaller DHBs had greater provision within this group of the population, with the five smallest DHBs by population having ASRs of at least 400/100,000 pys, a rate which was not reached for the most deprived deciles in any of the other larger DHBs.

Discussion

This study demonstrates that national rates of publicly-funded elective hip and knee TJR procedures have not increased beyond their 2007 peak. Higher rates were observed in older adults, females, those not living in 'Rural' or 'Main Urban Areas' and those living in areas of greater social deprivation. Rates varied between DHBs, even when age- and ethnicity-standardised. In general, there were higher rates of the provision of publicly-funded hip and knee TJR procedures among the smallest DHBs in New Zealand compared with the largest population DHBs in 2012–13.

A strength of this study was the use of consistently collected data for the entire New Zealand population. A limitation is that domicile was obtained from the National Health Index database which is updated when patients present at their DHB and therefore may no longer reflect the domicile as it was at the time of surgery for all participants. This study is restricted to publicly-funded procedures, therefore it does not consider the overall provision of TJR surgery, some of which are privately-funded. Comparing NMDS discharge data of publicly-funded hip and knee TJR with National Joint Registry data which includes both privately- and publicly-funded procedures,[4] it appears that approximately 65% of TJR were publicly-funded in New Zealand between 2006–2012. The provision of privately-funded procedures may vary by DHB and may influence the provision of publicly-funded procedures. Derrett et al[11] previously reported that DHBs with low rates of publicly-funded hip and knee TJR procedures had high rates of privately-funded procedures. A further limitation of our analyses is that we have reported on the provision of TJR; provision does not necessarily reflect demand for procedures or the severity of disease. Previous research has suggested that there is unmet need for these procedures in New Zealand.[9,13] Demand may vary across the country[9] and in some DHBs, 33–41% of patients listed for TJR are being returned to their General Practitioner without surgery due to waiting time targets.[20] There was an increase in the number of publicly-funded hip and knee TJR procedures carried out nationally between 2006 and 2013 in those aged 20 years and over. However, the bulk of the increase in both numbers and rate occurred between 2006 and 2007 as the Orthopaedic Joint Initiative ("…a programme of increased funding specifically targeting major joint replacement…") (p.15)[21] finished. During the period of this study, 2006–2013, the rate was highest in 2007. Between 2007 and 2013 the number of publicly-funded TJR procedures increased by 486 (6%) but the rate decreased by 0.6% suggesting that the increased number of publicly-funded TJR procedures is barely keeping up with population increases. Hooper et al[22] have predicted that numbers of hip and knee replacements will increase significantly by 2026. Such a predicted increase has clear implications for public funding of TJRs. The highest rate of hip and knee TJR procedures was for those people aged 75–84 years followed by 65–74 year olds. This is not surprising and aligns with the higher prevalence of OA among older age groups.[5] As life expectancy increases, it is likely that demand in the over 85 year-olds will increase.

Although the rate of procedures was higher among females, the difference between males and females was relatively small and probably reflects the higher prevalence of OA among women.[5]

Nationally, people in the least deprived deciles had the lowest rate of publicly-funded TJR procedures while those in the most deprived deciles had the highest rate. This is open to a number of different interpretations. Poorer access to medical care in the lower deciles might be expected to lead to a decreased rate of TJR rather than the increased rate seen. It is likely that there is greater use of private surgery by those of higher socio-economic status either through insurance or self-funding. However the findings may also reflect greater need for TJR among people of lower socio-economic status (for example, if need is related to type of occupation). However, no direct link between socio-economic deprivation and joint replacement has yet been identified other than possibly obesity; people in the most deprived areas of New Zealand having higher rates of obesity compared with those in the least deprived areas.[23]

Nationally, by prioritised ethnicity, Māori had the highest ASR of publicly-funded TJR

procedures. In a series of patients from a regional registry, Singleton et al[24] found that Māori were younger, had poorer pre-operative function than non-Māori patients and comprised 13.7% of their TJR procedures but only 11.2% of their population. Hooper et al[22] reported a relative rate in Māori of 0.72 for hip and 0.76 for knee TJR compared with those of 'European' ethnicity using data from the New Zealand Joint Registry. The main differences between that study and the current study are that privately-funded and acute procedures are included in the Joint Registry figures and that their analysis was based on joints not procedures. Their use of total response rather than prioritised ethnicity will not affect the rate for Māori as Māori are given top priority in our analysis by prioritised ethnicity. It is possible that lower rates of private utilisation among Māori may explain the difference in findings. It is not clear whether the higher rate of TJR in the current study is a reflection of an additional need among Māori or whether it is due to greater demand in the public sector due to lower private provision. It has been recognised previously that ethnicity data collected in the NMDS may undercount people of Māori ethnicity[25] which may have influenced the findings of this study. However, if Māori undergoing TJR surgery were less likely to be classified as Māori in the NMDS, the rate reported for Māori would be an under-estimate. It is unclear why rates were substantially lower among those of Asian ethnicity compared with those of Māori, Pacific or 'Other' ethnicities. It is possible that this may relate to more privately-funded procedures among this ethnic group. However Hooper et al[22] found similar results while including privately-funded procedures and suggested that older Asians living in New Zealand may return to their home country for joint surgery.[22] The ASR of TJR for people of Pacific ethnicity was over twice the rate for those of Asian ethnicity but was still significantly lower than the rate for those of Māori and 'Other' ethnicities. It is unclear why this is the case given Pacific people are highly represented in the most deprived areas of New Zealand and have higher rates of obesity compared with other ethnicities.[23] As the DHB-level denominator data was only available by 'prioritised ethnicity,' estimates for Pacific people do not include those who identified with both Māori and Pacific ethnic groups. Similarly, those who responded as being of both Pacific and Asian ethnicity are only included as Pacific.

There were differences in procedure rates by rurality with the highest rate for those living in 'Other Urban Areas' and the lowest rate for those in 'Main Urban Areas.' The lower rate for those living in 'Main Urban Areas' may have been influenced by a greater availability of private procedures in these areas but we cannot determine that in this study. While there may be some relationship between rurality and DHB-specific rates, the denominator data available for this analysis precluded examining this.

In the current study, AESRs varied by DHB with a 3.8 fold rate variation between lowest and highest in 2006–07 and a two-fold rate variation in 2012–13. However, if one outlier was excluded, there was no statistically significant change in the variation between DHBs from 2006–07 to 2012–13. In other words, there has been no apparent improvement in the equity of provision of publicly-funded TJR across DHBs over the eight years of the study period. Derrett et al,[11] although not standardising for ethnicity and also including revision procedures, reported nearly a five-fold variation of ASRs for publicly-funded TJR between DHBs in 2001–2002. They also reported geographic inequity for those in the poorest three deciles and found that rates of publicly-funded procedures were lowest for this group of people in DHBs that had the highest rates of privately-funded procedures.[11] Examining the ASR of publicly-funded TJR procedures by DHB for those in the most deprived deciles in the current study also found that rates varied considerably.

The larger DHBs typically had lower rates of publicly-funded TJR compared with the smaller DHBs and five of the eight largest DHBs had rates that were below the New Zealand average in 2012–13. These findings indicate that those living within the largest DHBs (by population) may be disadvantaged in terms of access to publicly-funded hip and knee TJR surgery. We cannot determine the reasons behind these findings. There may be greater access to private surgery in the larger DHB regions which may reduce

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the demand for public surgery. It has also been suggested that higher rates of private surgery could lead to lower rates of publicly-funded surgery due to surgeons not being available for public work.[11] Other factors such as high acute loads and complex tertiary referrals, which are likely to be more common in larger DHBs, may also influence access to publicly-funded procedures.

Conclusion

Despite an increase in the number of publicly-funded hip and knee TJR procedures between 2006 and 2013, the national increase in rate has been negligible since 2007 suggesting that the increased number of procedures may be only just keeping up with increases in the population. While the data demonstrated higher rates in older adults, females, people of Māori ethnicity, and those living in areas of greater social deprivation and 'other urban areas,' there was no systematic evidence of inequities disadvantaging vulnerable, higher needs or isolated groups, although this study did not include privately-funded procedures. In general, there were higher rates of the provision of publicly-funded hip and knee TJR procedures among the smallest DHBs in New Zealand, by population, compared with the largest population DHBs. The finding that rates vary between DHBs, even when age- and ethnicity- standardised, suggest equity among DHBs is not being achieved nationally. This indicates that further work is required to meet one of the key objectives in the New Zealand Ministry of Health's programme for elective surgery which is to "Work towards everyone having equal access to elective surgery no matter where they live".[26] Further research, using validated scoring tools, is needed to compare access to TJR according to need and to examine reasons behind differences in provision.

Competing interests:
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Non-resident orthopaedic admissions to Dunedin Hospital, New Zealand: 1997 to 2004

David Gwynne Jones

Abstract

Aims. The purpose of this study is to audit the numbers of non-residents requiring orthopaedic admission to our hospital and determine the effect of increasing tourist numbers and changes in Accident ACC regulations on healthcare resources.

Methods. Details of non-resident orthopaedic admissions for fiscal years 1997/8 to 2003/4 were analysed with respect to country of residence, mechanism of injury, case weights consumed, and actual costs.

Results. There has been no change in numbers of admissions or cost, averaging 32 cases (50 case weights [CWs]) per year. Most patients came from Asia (59 cases; 26%), then Australia (52 cases; 23%) and UK (40 cases; 18%). Snowsports accounted for 40% of admissions, Motor vehicle accidents (MVA) for 17%, and falls for 29%. Non-resident, non-MVA admissions have averaged 21 CWs per year since the changes in ACC regulations in 1999.

Discussion. Despite increasing tourist numbers, there has been no increase in numbers or CW of non-residents requiring orthopaedic admission. Although representing only a small proportion of the orthopaedic budget, they generate many hidden costs. The 50 CWs annually equates to approximately 13 major joint replacements per year. The increase in CWs consumed due to the ACC changes have had no corresponding increase in contracted orthopaedic volumes.

There has been a much heralded increase in tourist numbers to New Zealand in the past decade. In Otago, there has been an expansion in skifields and other adventure tourist activities. There are invariably accidents leading to overseas patients requiring admission for acute orthopaedic surgery. Tourists have a high profile on the ward, and create a large amount of work for nursing, medical, and administrative staff. They also generate costs which are not reflected in hospital-coding and reporting systems.

Patients from Australia and UK are eligible for healthcare in New Zealand under reciprocal arrangements. Prior to 1 July 1999, non-resident patients with accidental injuries were only covered by the Accident Compensation Corporation (ACC) if involved in a motor vehicle accident (MVA). Since July 1999, however, all non-residents with accidental injuries are covered by ACC at no cost to themselves while in New Zealand.[1]

Under transitional arrangements which ended in July 2002, hospitals could bill the Ministry of Health for non-resident, non-MVA cases. The hospital is bulk funded by ACC for the acute care of all patients sustaining accidental injury. The contracted volume of elective and acute orthopaedic surgery is calculated by case weights (CWs).

Any increase in acute case weights negatively impacts on the elective surgery volumes. The value of a case weight has varied over the study period from NZ$2478 to $2565 (2004) and is currently valued at $2855.

The purpose of this study is to audit the numbers of non-residents requiring admission to the orthopaedic wards, their country of origin, and mechanism of injury; and also to determine whether the increasing tourist numbers and the change in ACC regulations are having an impact on healthcare resources.

Materials and methods

All patients admitted under orthopaedic surgery for fiscal years ending June1998 to June 2004 with an overseas home address were identified from the Dunedin Hospital patient administration system. Records were cross-checked with ward and in-patient records. Students and people in employment were excluded. The demographics of the patients were recorded including age, sex, cause of injury, diagnosis, and country of residence. The case weights consumed and hence 'revenue' to the department was recorded. The actual cost to the hospital was estimated by the monitoring systems used by the Otago District Health Board (ODHB). Patient and billing details were cross-referenced with ODHB invoices to the Ministry of Health for non-resident, non-MVA patients.

Results

Patients—There has been little change in numbers of overseas patients during the previous 7 years; averaging 32 cases per year (Figure 1). Most patients came from Asia (59 cases, 26%), then Australia (52 cases, 23%) and UK (40 cases 18%) respectively (Figure 2).

Mechanism of injury—The commonest cause of injury was skiing or snowboarding, with 89 admissions (13 per year, range 8–16) comprising 40% of all non-resident admissions over the study period. Motor vehicle accidents made up 39 admissions (17%), while falls comprised 64 cases (29%). Commercial or organised tourist activities (such as parachuting, fly-by-wire, go-karting) counted for 21 cases (9.3%).

Cost—The case weights consumed have ranged from 42.8–55.5 per year with a mean of 50 CWs per year (Figure 1). The monetary value of 50 CWs is approximately $128,000 per year from the department budget. The estimated actual cost is $155,526. The contracted volumes for the Orthopaedic Department have remained relatively constant for the years 2001–2004. The current budget is 4332 CWs/year, so overseas admissions represent 1.1% of the total workload of the department. Skiing and snowboarding accidents, motor vehicle accidents, and falls contributed fairly equally to the numbers of CWs consumed. (Table 1)

ACC changes—For the years 1997/8 and 1999/9 (prior to the ACC changes), there were on average 17 non-resident patients (17.5 CWs) requiring admission for non-MVA accidents. The actual cost was $49,613 while revenue for these years averaged $62,276. Since the ACC changes, there have been an average 13.6 cases per year in this category who have accounted for a mean 21.1 CWs per year ($53,655), with an estimated actual cost of $64,369 per year.

Figure 1. Numbers of overseas patients and case weights consumed in fiscal years 1998 to 2004

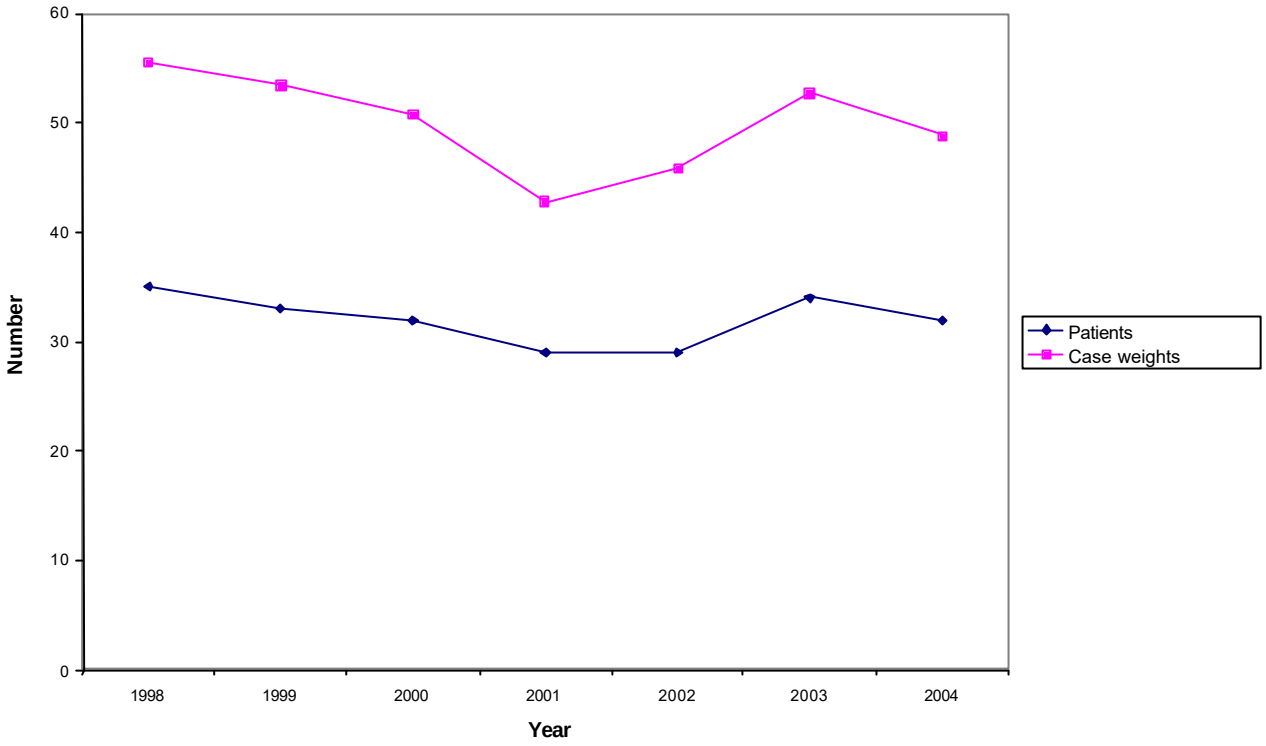


Figure 2. Countries and continents of residence of patients requiring orthopaedic admission in fiscal years 1998 to 2004

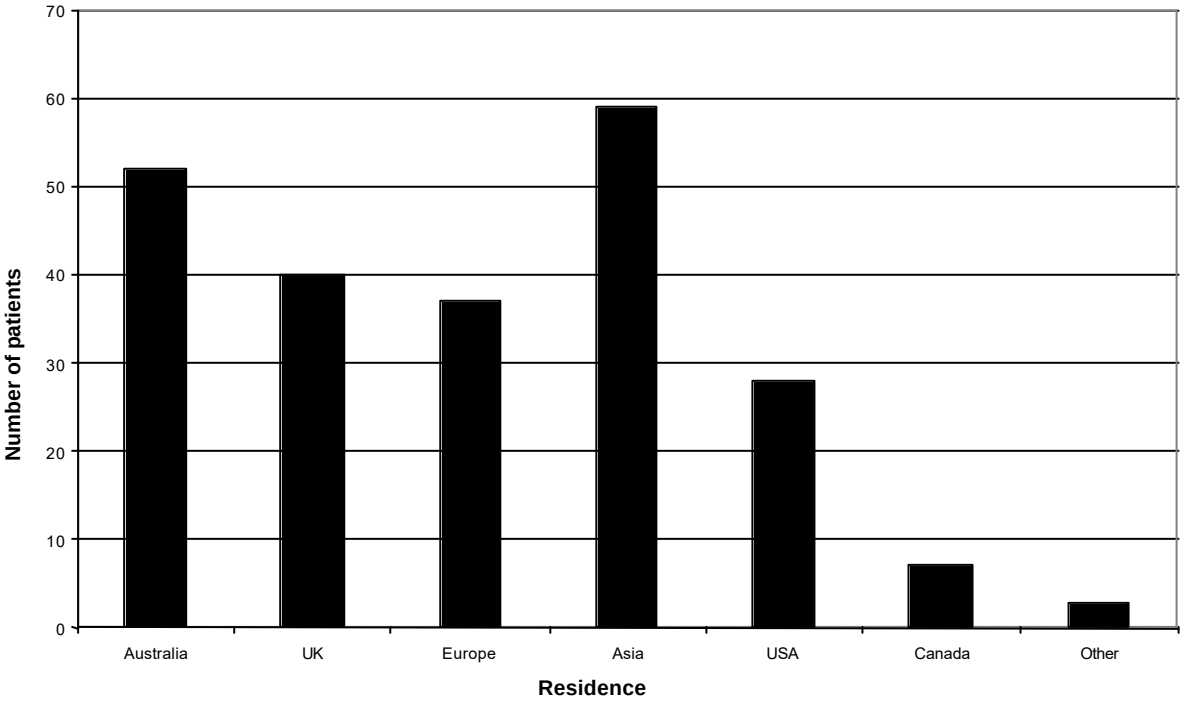
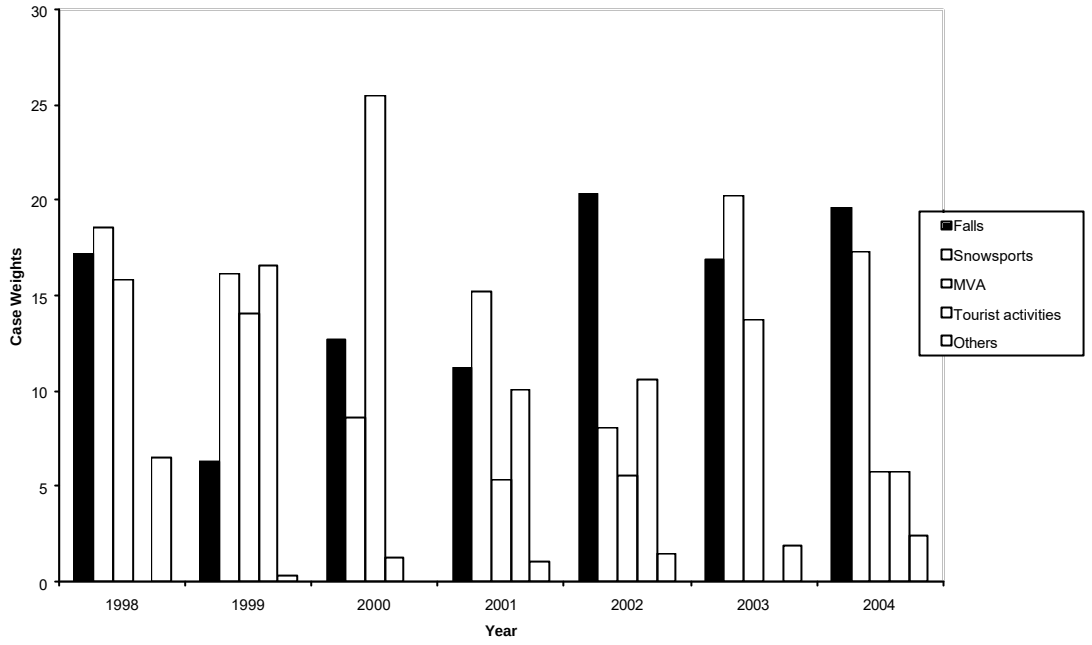


Figure 3. Case weights consumed by mechanism of injury 1998-2004



For fiscal years ending 2000, 2001, and 2002, an average of 13 CWs ($32,364) per year were refunded by the Ministry of Health to the Hospital under transitional arrangements. Since this arrangement has ceased, there has been no corresponding increase in orthopaedic volumes contracted by ODHB.

Table 1. Dunedin Hospital admissions and case weights by mechanism of injury for fiscal years ending 1998-2004

Variable	Snowsports	MVAs	Falls	Tourist activities	Other
Admissions	89	39	64	25	7
Total CWs	104	85.6	104.2	44.3	13.6
CWs/year	14.9	12.2	15.3	5.7	1.9
Actual cost/year	$45703	$40140	$45303	$20009	$4058

CWs=case weights; MVA=motor vehicle accidents, Tourist activities=commercial activities such as parachuting, fly-by-wire, and go-karting.

Discussion

There has been a 43% increase in visitor arrivals to New Zealand: from 1.48 million in 1998 to 2.11 million in 2003.[2] Tourist numbers in the Otago region would be expected to have similarly increased. Indeed, a common perception, both in the hospital and in the lay press,[3,4] is that there are increasing numbers of tourists requiring orthopaedic admission due to snowsport injuries and motor vehicle accidents. However, this study shows that the number of non-residents requiring orthopaedic admission has not increased significantly over the previous 7 years (1997 to 2004). Patients from Asia make up the largest proportion of orthopaedic admissions (26%), followed by Australia (23%) and the UK (18%).

Whilst Australians make up 33% of visitor numbers to New Zealand (Asians are 24% and UK residents 11%, respectively), the figures for visitor nights are: Asia 20%, Australia 19.7%, UK 18.0%, USA and Canada 10.6%, and Europe 8.7% thus reflecting varying lengths of stay among those groups (2003 figures).[2]

Snowsports, as expected, were the commonest reason for the accident. According to ACC figures, skifield visits doubled from 1998 to 2001 with 1.25 million visits in New Zealand in 2001. Snowsport injuries cost ACC $3.7 million in 2003.[5] New Zealand skifields estimate an injury rate of less than 5/1000 participants compared to international figures of 8 per 1000.[3] The cost of inpatient snowsport injuries was relatively low, averaging 1.17 CWs or $3600 actual costs per patient.

In contrast, there were fewer MVAs involving tourists but each admission averaged 2.2 CW and cost an average of $7216 thus reflecting the greater severity of injuries associated with higher velocity mechanisms.

Tourists have a high profile on the ward because of the need for translators, the lack of family support, international telephone calls, and the involvement of insurance companies and airlines in discharge planning. This creates a large amount of work for nursing, medical, and administrative staff and hidden costs which are not reflected in hospital coding and reporting systems.

The cost and case weights consumed is only a small proportion of the orthopaedic budget averaging around 1%. However, these 50 CWs represent approximately 13 major joint replacements per year. The change in ACC regulations have meant that an average of 21 CW/year are now coming from the orthopaedic budget with no corresponding increase in contracted volume.

Despite an increase in the number of tourists there has not been an increase in numbers or case weight load of non-residents requiring orthopaedic admission over the previous 7 years. The changes in ACC regulations have had a small impact on the provision of orthopaedic services in the Otago region.

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Non-resident orthopaedic admissions to Dunedin Hospital 1997 to 2017 and Southland Hospital 2011 to 2017

Annabel Merrett, Jennifer Keys, Chris Crane, David Gwynne-Jones

ABSTRACT

AIMS: The purpose of this study is to audit the numbers of non-residents requiring orthopaedic admission to Dunedin and Southland Hospitals and determine the effects of increasing tourist numbers on healthcare resources.

METHOD: All non-resident orthopaedic admissions to Dunedin Hospital from January 2005 to December 2017 and Invercargill Hospital from January 2011 to December 2017 were analysed with respect to country of residence, mechanism of injury, primary diagnosis and case weights consumed. The results were combined with figures from 1997–2004 to give a 21-year series for Dunedin Hospital.

RESULTS: There has been a significant increase in the number of admissions and case weights (CW) over the past 21 years at Dunedin Hospital ($p<0.001$). The most common mechanisms of injury were snow sports at Dunedin Hospital and falls for Southland Hospital. Between 2011 and 2017 there were on average 50 non-resident admissions per year (92.9 CW/year) to Dunedin Hospital and 74 admissions (120.7 CW/year) in Southland.

CONCLUSION: Increasing tourist numbers have resulted in an increase number of orthopaedic admissions to Dunedin Hospital over the last two decades although it remains a small proportion of the total workload. Southland Hospital is relatively more affected. These patients represent an annual cost in excess of $1,000,000 to Southern DHB.

Over the past several decades, New Zealand's tourism industry has experienced exceptional growth, and forecasts for the sector indicate this expansion will continue. Statistics New Zealand has recorded that New Zealand attracted 3.5 million international visitors in the year ending December 2016.[1] This has risen from 1.48 million in 1998 and is projected to increase to 4.5 million by 2022.[1,2]

In the Otago and Southland regions, due to the popularity of the tourist resorts of Queenstown and Wanaka, there is a higher ratio of international tourists to local residents and a forecast growth in tourism that is higher than for other regions. This puts relatively higher pressure on the local infrastructure, including healthcare, compared to other regions.[2] In overseas studies the most common reason for admission for overseas residents is trauma.[3,4] In New Zealand in general, and Otago and Southland in particular, adventure tourism, snow sports and motor vehicle accidents involving overseas drivers may all lead to admissions to the orthopaedic service. Concerns over this burden has led to previous studies looking at overseas admissions to Dunedin Hospital from 1997–2004 and snow sports injuries admitted to Invercargill during 2009.[5,6]

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Each DHB receives funding according to the population-based funding formula (PBFF). Public Health Acute services (PHAS) are funded from this. Since July 1999, all non-residents with accidental injuries are covered by the Accident Compensation Corporation (ACC) while in New Zealand. Prior to 1999, non-residents were only covered by the ACC if their injury was the result of a motor vehicle accident. The DHB are expected to cover all acute costs through PHAS, from their bulk funding. The Crown recovers these costs from ACC at a national level but not directly to individual DHBs. Therefore the cost of treating patients from overseas comes directly from the base funding of the DHB.

The Otago DHB and Southland DHBs merged in 2010 to form the Southern DHB (SDHB).The Southern DHB has had well-publicised problems with a financial deficit and difficulties with access to elective orthopaedic surgery.[7,8] Any increase in non-resident admissions over and above normal adjustments may have impacts on healthcare costs and directly and indirectly on elective service delivery.

The base hospitals in Dunedin and Invercargill both provide an orthopaedic trauma service. Patients from Queenstown have traditionally been transferred to Invercargill and those from Wanaka and Central Otago to Dunedin. Due to the nature and increased volume of tourism throughout the district it is hypothesised that there will have been an increase in overseas orthopaedic admissions since our original study.

The primary objective of this study is to audit the numbers and details of non-resident orthopaedic admissions to Dunedin Hospital over the 21-year period 1997 to 2017. The secondary outcome is to compare the equivalent figures from 2011 to 2017 for Southland to determine the overall impact on Southern DHB.

Materials and Methods

We used the same methodology as for our previous study.[5] Hospital administration systems were used to identify all non-resident patients that were admitted under orthopaedic surgery from January 2005 to December 2017 for Dunedin Hospital, and January 2011 to December 2017 for Southland Hospital. The search included residency status of all patients and overseas address, which is determined at the time of admission and captured in the electronic record. Patients who were students or people in employment in New Zealand including those on working visas were excluded as in our previous study. All cases identified were individually checked including a review of admission notes if required. The demographics of the patients were recorded, including age, sex, country of residence, mechanism of injury and primary diagnosis. The case weights (CW) consumed were also recorded. The price per CW in 2017 was $4,921 and allowed the cost to the hospital was estimated. The proportion of the total orthopaedic workload was then calculated based on both total discharges and CWs from DHB reporting systems for both hospitals.

The results of this study were then combined with the previous study to create one continuous data set for numbers of patients and case weights consumed from January 1997 to December 2017 for Dunedin Hospital.

Results

Dunedin site 2005–2017

There were a total of 651 patients admitted (mean 50/year). The average length of stay (LOS) was 4.9 days (median three days). There were a total of 3,128 bed nights used over this period (240/year). The total case weights were 1,159 (mean 89.1/year).

The majority of patients in Dunedin come from Australia (201 patients, 31.0%), followed by the UK (115 patients, 17.7%) and Europe (111 patients, 17.1%,). Despite increasing numbers of Asian tourists there were only 88 patients (13.6%) during this time.

Mechanism of injury

The most common cause of injury was skiing and snowboarding with 200 admissions (mean 15.4 admissions per year), comprising 30% of all non-resident admissions. Falls were the second most common cause with 168 admissions (26%) (13/year). Motor vehicle accidents (MVAs) caused 83 admissions (13%) (6/year) with bicycle accidents causing 41 admissions (6%) (3/ year). Commercial tourist activities such as para-

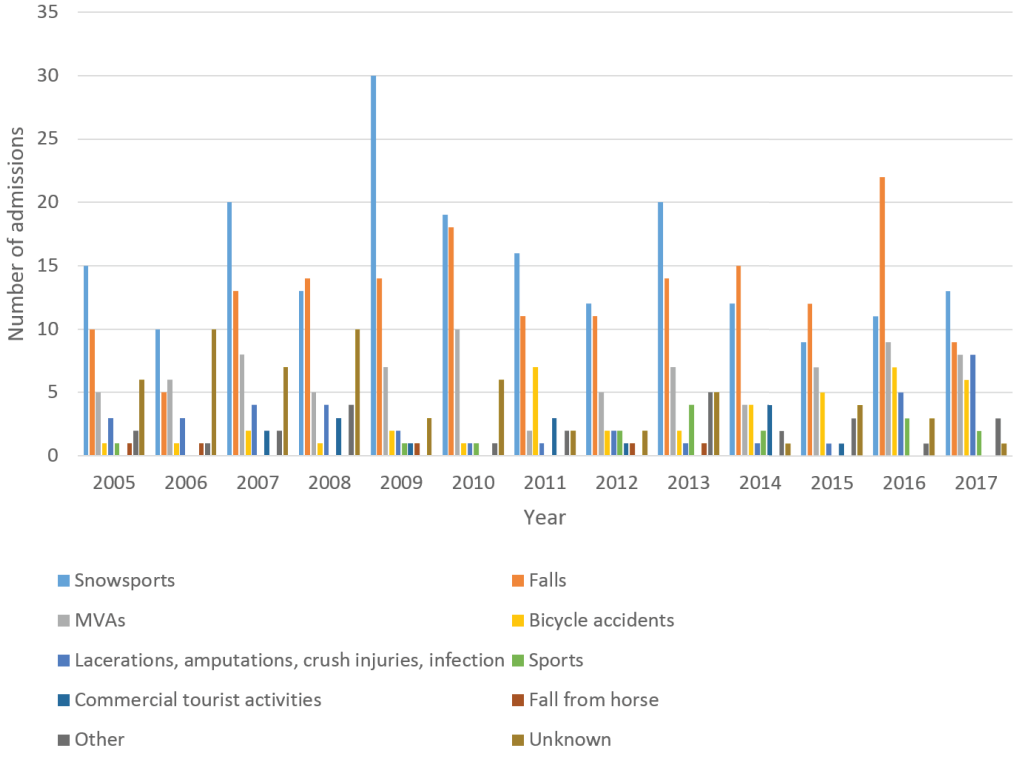
Table 1: Details of mechanism of injury and case weights for non-resident orthopaedic admissions to Dunedin Hospital 2005–2017 and Southland Hospital 2011–17.

	Dunedin 2005–2017				Southland 2011–2017			
Mechanism	**Number**	**%**	**CW**	**CW/D**	**Number**	**%**	**CW**	**CW/D**
Snowsports	200	30	346	1.7	141	27	217	1.5
Falls	168	26	294	1.8	161	31	312	1.9
MVAs	83	13	230	2.8	42	8	76.4	1.8
Fall from bike	41	6	66	1.6	59	11	87	1.5
Lacerations, amputations, crush injuries and infection	36	6	36	1.0	27	5	34	1.3
Sports	16	2	34	2.1	10	2	14.2	1.4
Commercial tourist activities	15	2	36	2.4	30	6	43.7	1.5
Fall from horse	5	1	6	1.2	11	2	23.9	2.2
Other	26	4	43	1.7	12	2	10.9	0.9
Unknown	61	9	68	1.1	24	5	25.6	1.1
Total	651	100	1,159	1.8	517	100	845	1.6

CW; Case Weight, CW/D; Case weight/discharge, MVA; Motor vehicle Accident.

gliding, bungy jumping and canyoning only led to 15 admissions (2%) over the 13-year period (Figure 1). The mean case weight per discharge (CW/D) was 2.8 for patients admitted due to MVAs, 2.4 for commercial tourist activities and 1.6 to 1.8 for snow sports, falls and bicycle accidents (Table 1).

Figure 1: Numbers of non-resident orthopaedic admissions to Dunedin Hospital by mechanism of injury 2005 to 2017.



Commercial tourist activities include: canyoning, parachuting, jetboating, skydiving, hang gliding, scenic flights, go-karting, bungy jumping, fly-by-wire and paragliding.

Table 2: Details of injury for non-resident orthopaedic admissions to Dunedin Hospital 2005–2017.

Primary diagnosis	Number of patients	%	CW
Lower limb fractures and dislocations	272	42	557
Upper limb fractures and dislocations	181	28	280
Spinal injuries	47	7	80
Hip and pelvis fractures and dislocations	31	5	55
Laceration, crush injuries and amputations	24	4	24
Tendon and ligament injuries	28	4	36
Infection and soft tissue injuries	24	4	26
Multiple fractures and injuries	8	1	42
Other	18	3	59
Unknown	18	3	
Total	**651**	**100**	**1,159**

The most common injuries seen were lower limb fractures and dislocations, which made up 42% of admissions followed by upper limb fractures (28%) with 47 patients (7%) having spinal injuries (Table 2).

Changes 1997–2017

Linear regression analysis shows a significant increase in numbers of non-resident patients (p=0.0002) and case weights (p=0.006) consumed in Dunedin Hospital during the previous 21 years (Figure 2). Numbers have increased from 32 patients per year from 1997–2004 to 50 patients a year (+60%). The case weights ranged between 44 CW (2001) and 133 CW (2016). The mean case weight/year from 1997–2004 was 50, rising to 85.5 CW/year for the period 2005–2010 and 92.9 CW/year between 2011 and 2017. This represents an 86% increase. The mean CW/D has increased from 1.67 (1997–2004) to 1.9 (2011–17) (+14%).

Figure 2: Number and case weights of non-resident orthopaedic admissions to Dunedin Hospital, January 1997 to October 2017.

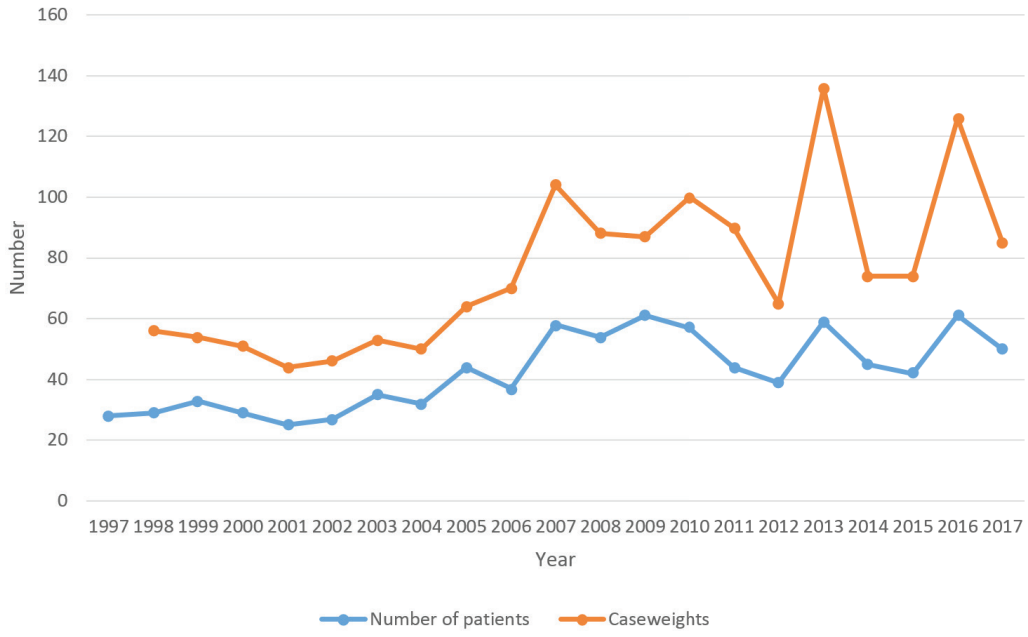
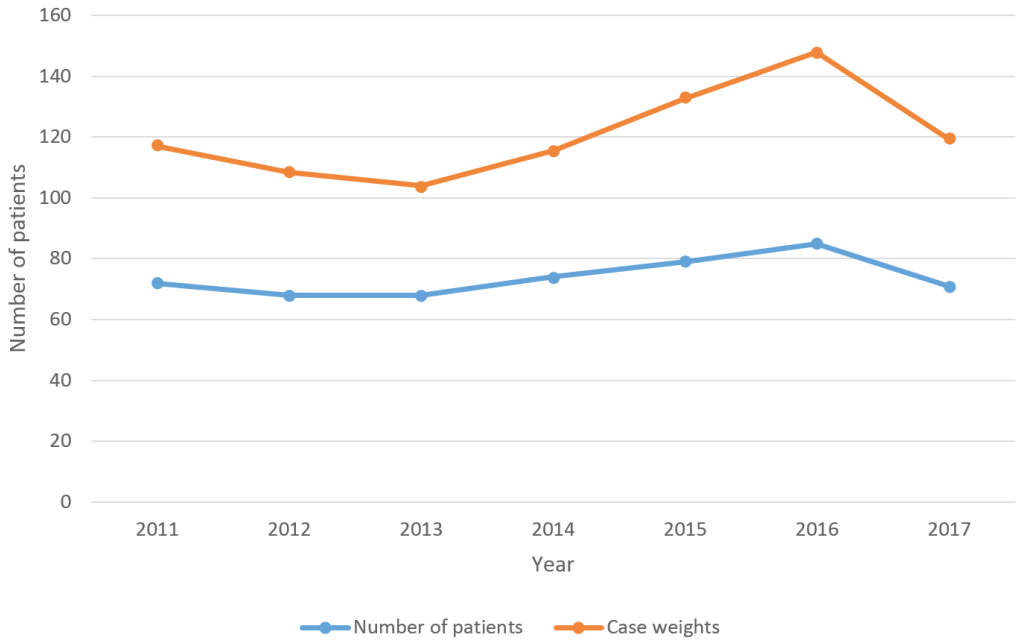


Figure 3: Number and case weights of non-resident orthopaedic admissions to Invercargill Hospital 2011–2017.



Southland site 2011 to 2017

At Southland Hospital there were a total of 517 admissions (845CW) over the seven-year period. The average was 74 discharges/year (120.7 CW/year). The numbers also showed a rising trend though there was a dip in 2017 (linear regression p= 0.23, ns) (Figure 3). The case weights consumed for non-resident orthopaedic admissions are also showed an increasing trend year to year with the exception of 2017 (linear regression, p=0.17) (Figure 3). The mean LOS was 3.6 days, (median 3) with an average of 270 bed nights per year.

Patients most commonly were from Australia (226, 43.7%), followed by UK (80, 15.5%), and Europe (77, 14.9%) and Asia. Australians made up a significantly higher proportion of admissions in Southland than in Dunedin (Fisher exact test, p<0.001).

Falls were the most common cause of admission with 161 admissions (23 per year, 31.1% of all non-resident admissions), followed by skiing and snowboarding with 141 admissions (20.1 per year, 27.3% of all non-resident admissions), and bicycle accidents with 59 admissions (8.4 per year, 11.4% of all non-resident admissions). Commercial tourist activities led to 30 admissions (5.8%) (Table 1).

The mean CW/discharge was lower in Southland at 1.6 CW compared to 1.8 CW in Dunedin. The mean CW/discharge was highest for falls from horse (2.2), falls (1.9) and MVAs at 1.8 CW/D and 1.5 CW/D for snow sports, bicycle accidents and commercial tourist activities.

There was a similar mix of injuries to Dunedin with lower limb fractures most common (39%), then upper limb fractures (34%) but a higher proportion of spinal injuries at 72 (13%).

Proportion of workload in Southern DHB

In 2004 the total orthopaedic budget in Dunedin was 4,332 CW. In 2017 this had risen to 6,421 CW. The proportion consumed by overseas patients was 1.1% in the period 1997–2005. Between 2007–17 this had increased to 1.6% of total CW and 1.8% of all discharges. Overseas cases accounted for 3.1% of acute admissions and CWs. In dollar terms, using 2017 CW values, the cost in Dunedin was $620,046 in 2016 and $418,285 in 2017.

In Southland overseas cases accounted for 3.9% of all discharges and 3.8% of total CW for the period 2011–17. They accounted for 6.9% of acute admissions and 7.2%

acute CWs during this period. The cost was $728,000 in 2016 and $585,600 in 2017.

The cost for Southern DHB for the seven-year period 2011–17 has averaged 214 CW or 2.3% of the total orthopaedic budget. Using 2017 values, this represents an average annual cost of $1,051,125 (range $853,795 to $1,348,354).

Discussion

With the increase in tourist numbers in New Zealand, there has been a subsequent increase in the number of non-resident admissions and case weights consumed over the past 21 years for Dunedin hospital, and over the seven-year study period at Southland Hospital. The commonest causes of admission are due to snow sports, MVAs and falls. Australian residents compromise the largest proportion of admissions. Overseas admissions only comprise 3.1% of the acute orthopaedic budget in Dunedin but 7.2% in Southland, which is disproportionately affected.

In the six years (2010–2016) there was a 27.9% increase in annual visitor arrivals to New Zealand (2,525,044–3,499,939).[1] This increase in tourist numbers has occurred throughout New Zealand, including Otago and Southland. In Otago in 2015, the ratio of annual visitor count to resident population was 4.9, which was the second highest ratio in New Zealand, after the West Coast.[2] Therefore, it would be expected that this rise in tourism would lead to an increase in non-resident hospital admissions.

Our previous study showed that while there was a 43% increase in visitor arrival to New Zealand between 1997 and 2004, there was no significant increase in the number of non-resident orthopaedic admissions at Dunedin hospital over that time period.[5] However, over the 21-year period between 1997 and 2017, there is an increasing trend in terms of numbers of non-resident admissions, case weights consumed and the proportion of the total orthopaedic budget at Dunedin Hospital. Between 1997 and 2004 there were on average 32 patients per year, which has increased by 50% to 49 during the last seven years of this study. Southland Hospital carries a higher burden than Dunedin with 74 non-resident orthopaedic patients/year accounting for 3.8% of the total orthopaedic budget. The appointment of a trauma surgeon in Southland has meant that fewer patients are transferred out to larger centres. However, the CW/D ratio is lower for Southland than Dunedin suggesting that it is high numbers of less complex cases that makes up the bulk of their load.

From 2012 to 2016, tourists from Australia made up 40% of our annual visitors, those from Asia made up 23%, and tourists from the US and UK made up 8% and 6% respectively.[1] As expected, patients from Australia make up the largest proportion of orthopaedic admissions (31% at Dunedin hospital, 43.7% at Invercargill Hospital). This may be due to an increase in the number of direct flights into Queenstown Airport from Australia. However, those from Asia only made up 13.5% of admissions at Dunedin Hospital and 12.8% at Invercargill Hospital. This is in contrast to our previous paper covering 1997 to 2004 when patients from Asia made up the largest proportion of orthopaedic admissions (26%), followed by Australia (23%) and the UK (18%).[5]

It is a common perception that snow sport injuries and motor vehicle accidents (MVAs) are a major cause of non-residents' hospital admissions. This study confirmed that snow sports were the most common reason for admission at Dunedin Hospital and the second most common reason for admission at Invercargill Hospital. Burgess and Namazie[6] reported that in 2009, 59 overseas patients (85 CW) were admitted to Southland Hospital following snow sports injuries over a four-month period. This represented two-thirds of admissions for snow sport injuries over the same period. This is much higher than in subsequent years which suggests either that 2009 was a bad year prompting their study or safety measures in the snow sport industry have improved. They recorded country of origin and patients may have been categorised as an overseas patient even if they had a local address and were working or studying. In their study the average CW/D was 1.44 ($7,086, 2017 values) compared with 1.54 CW/D ($7,578) in Southland and 1.72 CW/D ($8,464) in Dunedin in in this study. This suggests that the severity of injury and hence cost is increasing.

There were fewer non-residents admitted after MVAs, however each admission cost an average of 2.8 CW ($13,779) for Dunedin Hospital, and 1.95 ($9,596) for Southland Hospital due to the greater severity of injuries. More seriously injured patients are usually transferred to Dunedin Hospital by rescue helicopter regardless of the location of their accident.

This study found that the average case weights per year from 2011 to 2017 was 92.9 CW for Dunedin Hospital and 120.7 CW for Invercargill, which equates to approximately $457,161 and $590,520 respectively (2017 values). In our previous study non-resident orthopaedic admissions accounted for 1.1% of the total orthopaedic workload.[5] This is now 1.6% in Dunedin and 3.9% in Southland. Consequently the burden of overseas residents on the service has increased in both absolute and relative terms. This is despite significant increases in the orthopaedic elective budget due to the Orthopaedic Joint Initiative and other policies.

There may be both direct and indirect consequences of this work on elective surgery. Bed block and theatre access problems can lead to cancellation of electives. The financial cost per year adds to the budget deficit and could be used to employ more staff. The cost and number of CWs/year across Southern DHB would equate to approximately 65 elective hip replacements.

A weakness of the study is that the inclusion criteria was to have an overseas home address listed on their patient records or in-patient notes. However, some overseas patients report a local address that they are currently staying at and may not have been identified as an overseas resident. However, residency status is routinely checked at the time of admission and was used to help identify non-residents. We excluded students studying in New Zealand and those in employment, for example on working visas, as they were considered to be paying New Zealand taxes. We used the same methodology in our previous study so that trends were more likely to be valid. However, the results are still likely to be an underestimate. Outpatient and fracture clinic costs for patients treated with more minor injuries have not been collected so the true cost to SDHB of injuries to overseas residents will be greater.

This study focused solely on Southern DHB and there is a lack of national data with which to compare these results. However, data presented at the NZOA trauma meeting this year suggests that the total overseas delivery funded through the Population-based funding formula (PBFF) in Southern DHB is the highest in New Zealand and in excess of $2 million.[10] Further work at a national level will help identify the workload caused by overseas tourists. If significant anomalies exist then this should have an impact on future funding decisions such as the mechanism used by ACC to fund acute care for each DHB.

Conclusion

Increasing tourist numbers have resulted in an increased number of orthopaedic admissions to Dunedin Hospital over the last two decades. It remains a small proportion of the total departmental workload while Southland Hospital is relatively more affected. These patients represent a cost in excess of $1,000,000 per annum to Southern DHB, which has to be funded from its share of population-based funding.

Competing interests:
Nil.
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The projected burden of knee osteoarthritis in New Zealand: healthcare expenditure and total joint provision

David Gwynne-Jones, Gary Hooper

We commend Wilson and Abbott on their paper highlighting the projected burden of knee osteoarthritis in New Zealand.[1] Their projections are worrying and match our previous findings.[2–4] However, we have concerns regarding the accuracy of their figures, the clinical implications and their conclusions. They underestimate the demand as the model does not allow for patients who need bilateral TKR and does not appear to include unicompartmental replacement (UKR), which is also performed for knee OA.

In 2013, 7,419 knee replacements were performed in New Zealand (6,694 TKR and 725 UKR), of which osteoarthritis was the diagnosis of 95%.[5] Therefore, the baseline number performed for OA was 7,048 rather than 5,070 used in their model. By 2017 there were 9,352 knee replacements (8,298 TKR and 1,054 UKR), so the burden for OA of approximately 8,884 is already well in excess of 5,770 in their model. It has already surpassed the 8,613 projected by Hooper et al for 2026[2] and is fast approaching the projections of Wilson and Abbott for 2038. The numbers performed in 2017 were 54% higher than Wilson and Abbott's estimate, so extrapolating from this the total burden could approach 14,000 TKR/UKR annually by 2038 or an increase of almost 7,000 from 2013.

They also modeled the effect of rising rates of obesity on projected numbers of patients needing TKR. Obesity has a major impact on a wide range of other orthopaedic conditions. Procedures are more complex, take longer and have higher complication rates. We fully concur with their conclusion that public health measures are needed to reduce population obesity rates. However, there will be a lead time of many years before we are likely to see any effect on demand for TKR.

While they state in their introduction that there are capacity constraints, they do not expand on this in the discussion. The average orthopaedic surgeon in New Zealand performs 36 TKR per year. This increases to 41 per year if UKR is also included.[5] To perform the additional 4,000 procedures predicted by Wilson and Abbott would potentially need a further 100 orthopaedic surgeons or an increase of 50% on the 206 surgeons who performed knee arthroplasty in 2013. In addition, there will be a need for more supporting staff (anaesthetists, nurses, physiotherapists, etc) and infrastructure (beds, operating facilities and surgical time).

In the discussion they state that "effective, low cost, early interventions such as exercise therapy, can alleviate symptoms, improve quality of life and reduce the need for costly treatment, such as TKR, later in the disease course." They conclude that without these changes the number of TKRs will increase by 4,000 by 2038 with a subsequent increase in the fiscal burden.

We agree that a more coordinated approach and effective non-operative treatment, including exercise therapy, has an important role in all patients with knee OA. However, the two papers they cite add

little to support the statement that TKR can be reduced in New Zealand by non-operative measures. The study by Teoh et al[6] is from Australia, which has a very different healthcare system and access thresholds to New Zealand. The MOA study from New Zealand only has follow-up to two years by which time 35% of patients had already undergone hip or knee replacement.[7] A recent study has shown that it may be possible to delay surgery for five years in up to 50% of patients who initially did not qualify for TKR with an individualised non-operative programme.[8] However, while they avoided surgery, they had no clinically relevant improvement.

Exercise therapy may be cost-effective in the short term, but TKR, while expensive up front, has been shown to be highly cost-effective with gains lasting many years.[9] The 18-year survival of a TKR in New Zealand is 92.3%, so for the majority of patients it is one procedure that will last their lifetime.[5]

The healthcare burden of knee OA and other musculoskeletal conditions will continue to grow. Robust modeling is important to help inform long-term funding decisions but should include a clinical perspective in order to be relevant and credible. Public health initiatives to reduce obesity are essential but the demand for TKR will continue to rise. We need to plan for this from both economic and workforce training perspectives. Unless adequate provision is made for TKR, the inevitable consequence will be rising threshold scores for publicly funded surgery, explicit rationing and increasing numbers of patients being declined surgery.[4]

Competing interests:
Nil.

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Chapter 2
Carpal tunnel syndrome (CTS) - a success story.

One of the highest volume procedures we perform is carpal tunnel decompression (CTD). This straightforward procedure can be performed endoscopically which may require general anaesthetic or regional nerve block and is also be performed by plastic surgeons or neurosurgeons sometimes using an operating microscope in a fully equipped theatre. In contrast in the public sector we usually perform it open, under local anaesthetic, in the day surgery unit (DSU) or on the Mobile Surgical Services bus by a consultant or suitably experienced registrar. Our ageing DSU comprises two small theatres of which the smaller is little more than a procedure room. The Mobile Surgical bus visits small centres such as Oamaru, Balclutha and Queenstown every 5 weeks. We have relatively good access and can treat 6-8 patients in a 4 hour session without the need for an anaesthetist. It has also freed up our fully equipped theatres for major procedures such as joint replacement. In addition we have enjoyed a first class service provided by Dr Peter Taylor, our neurophysiologist, who has a keen interest and contributed to several of the papers in this chapter. As a result of this approach we have provided CTD above the national rate for many years in marked contrast to joint replacement surgery.

In '*Incidence of Carpal Tunnel Syndrome Requiring Surgical Decompression: A 10.5-Year Review of 2,309 Patients*' we reported primarily on the epidemiology of CTS. We found that the highest rates of surgically treated CTS were found in the elderly rather than middle-aged women as traditionally thought. Over the age of 65 years males and females had an equal incidence. The neurophysiological changes were more severe with increasing age. This may account for previous reports that suggested that elderly patients are more likely to do poorly. This did not match our experience and led to an early publication '*The outcome of carpal tunnel decompression in elderly patients'.* In this we report good outcome scores in patients over 70 years that were comparable to those in younger patients in published studies, and a satisfaction rate of 94%.

Incidence of Carpal Tunnel Syndrome Requiring Surgical Decompression: A 10.5-Year Review of 2,309 Patients

John H. J. English, MB, ChB,* David P. Gwynne-Jones, BM, BCh*

Purpose To describe the demographics, neurophysiological grading, and incidence of patients undergoing carpal tunnel decompression (CTD) for carpal tunnel syndrome (CTS) in a single region.

Methods A retrospective review of 2,313 patients aged greater than 16 years who underwent 3,073 CTDs between January 2000 and August 2010. Crude annual and age- and sex-specific incidences were calculated for the study period. Nerve conduction study grades were recorded and compared with age and sex.

Results Of the 2,313 patients 1,419 (61%) were female and 890 (39%) were male. Mean age at surgery was 56 years (range, 16–93 years). Females had a significantly higher CTD incidence compared with males (161 vs 108/100,000 person-years, respectively). The highest rates of CTD were seen in the 70- to 79-year age group for both men and women (307/100,000 person-years). Neurophysiological grade increased in severity with increasing age despite using an age-adjusted grading system, with higher grades in patients aged greater than 65 years.

Conclusions This study suggests that carpal tunnel syndrome has the highest incidence in older people who tend to have more severe neurophysiological changes. *(J Hand Surg Am. 2015;40(12):2427–2434. Copyright © 2015 by the American Society for Surgery of the Hand. All rights reserved.)*

Type of study/level of evidence Prognostic II.

Key words Carpal tunnel syndrome, epidemiology, incidence.

CARPAL TUNNEL SYNDROME (CTS) is the most common upper limb entrapment neuropathy. Traditionally, it has been considered a disease of middle-aged women. In 1966, Phalen[1] stated that "the typical patient with this syndrome is a middle-aged housewife." Other studies have shown that it can occur frequently in older people and in young working individuals.[2–5] Recently, a higher surgical incidence has been reported in older women.[6] In our experience, CTS is often seen in both the elderly and in younger working individuals and middle-aged women.[2,3] It is a major cause of disability and has impacts both socially and economically, including lost days at work and sleep disturbance.[7,8] Refractory cases not responsive to conservative treatment will usually be treated with carpal tunnel decompression (CTD).[9]

The diagnosis is usually a clinical one based on history and examination.[10,11] Neurophysiological testing can be useful to confirm a clinical diagnosis of CTS and provide information on the severity of median nerve compression. It also allows for

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TABLE 1. Nerve Conduction Study Grading System, Otago, New Zealand

Grade	Palmar Latency	Sensory Conduction Velocity	Distal Motor Latency	Sensory Amplitude	Motor Amplitude
6 (severe)				Absent	Absent
5 (very marked)				> 7.0 SD or absent	and > 4.0 SD
4 (marked)		> 5.0 SD	or > 5.0 SD	and > 4.5 to < 7.0 SD or absent	or > 4.0 SD
3 (moderate)		> 4.0–5.0 SD	or > 4.0 to < 5.0 SD	and < 4.5 SD	or < 4.0 SD
2 (mild)	> 3.0 SD	or > 3.0–4.0 SD	or > 3.0 to < 4.0 SD	and < 3.0 SD	and < 3.0 SD
1 (borderline)	2.5–3.5 SD	and < 3.0 SD	and < 3.0 SD	and < 3.0 SD	and < 3.0 SD
0 (normal)	All < 2.5 SD	and < 2.5SD	and < 2.5 SD	and < 2.5 SD	and < 2.5 SD

For conduction velocity and amplitudes, SD refers to SDs less than the mean. For distal motor latencies and palmar latencies, SD refers to SDs greater than the mean.

monitoring unexpected outcomes such as incomplete decompression or nerve injury.[9]

The purpose of this study was to describe the epidemiology of CTS severe enough in a single region to require surgical release. Nerve conduction studies (NCS) were used to compare severity of median nerve compression with the age and sex of patients. This may then allow an estimate of the appropriate demand for CTD in a given population based on age and sex.

MATERIALS AND METHODS

Our region has a population estimate of 193,800 people, with 130,000 people living in the main city. It covers a large geographical area of 31,000 km^2, which is predominantly rural.[12] There is one university public hospital and a private hospital. Rural centers are serviced periodically by a publicly funded mobile surgical bus.

After we gained ethical approval from the Health and Disability Ethics Committee to perform a retrospective review, we collected details of all patients aged 16 years or older undergoing CTD between January 2000 and August 2010. These included public and private hospital patients, cases performed on the mobile surgical bus, and those performed as office procedures in private offices. Data were collected through a combination of hospital International Classification of Diseases codes, local surgical audit, surgical bus records, and private clinic and hospital records.

During the study period, all NCS were performed by the sole neurophysiologist in our region using standardized techniques. Nerve conduction study grades were expressed as SD away from an age- and body mass–adjusted population mean (Table 1).[3,13,14] Neurophysiological data were analyzed on 1,104 patients in the latter part of the study from 2005 to 2010. In patients with bilateral disease, the hand with the higher-grade neurophysiological change was used for the analysis. Our practice is to perform an open carpal tunnel release under local anesthesia as a day case. During the time of the study, all carpal tunnel procedures were performed by 1 of the 9 orthopedic surgeons or their residents. Indications for surgery were symptomatic CTS with confirmatory neurophysiological testing usually showing at least grade 3 (moderate) compression. Our country has free public surgery, and our region has good access to family doctors. During the study period, there was no noteworthy limitation on access to publicly funded carpal tunnel surgery.

Crude annual and age- and sex-specific incidences were calculated for the study period. The national census (2006) was used to obtain local population data.[12] The incidences were also standardized using World Health Organization European Standard population as the reference population.[15] We used Student *t* test to evaluate statistical differences in crude age- and sex-specific incidences. Chi-square test was used to evaluate statistical differences between a population aged less than 65 years and aged 65 years and older.

RESULTS

From January 2000 to August 2010, 2,313 patients underwent 3,073 CTDs. A total of 760 patients had bilateral procedures (simultaneous or staged); 1,419 patients were female (61%) and 890 were male (39%). Mean age at surgery was 56 years (confidence interval [CI], 55.7–57.0) for both males (range, 17–91 years) and females (range, 16–93 years).

Mean number of CTDs per year was 217. There was no significant change in number of CTDs over the first and second halves of the study period. Mean

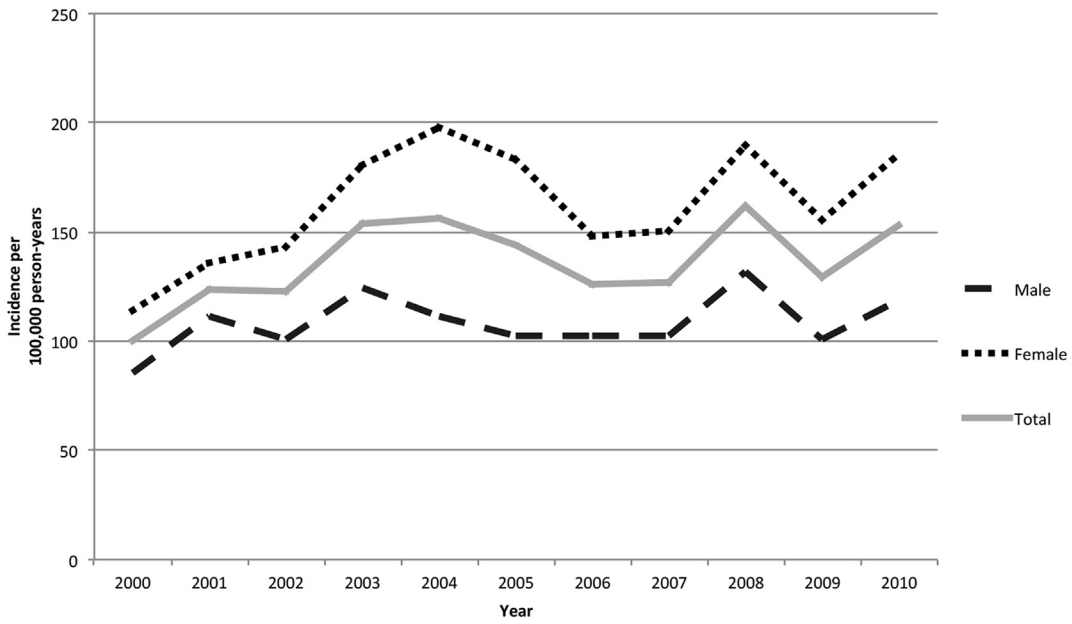

FIGURE 1: Annual crude and sex-specific incidence (per 100,000 person-years). Note: Year 2010 has been adjusted to an estimate of a full year.

number of CTDs in males per year (83; CI, 75−92) was significantly lower than females (133; CI, 117−149) ($P < .001$) (Fig. 1).

The annual average crude incidence (2000−2010) was 136/100,000 person-years (CI, 121−150) and the age-standardized (AS) incidence was similar, at 137/100,000 person-years. The sex-specific incidence showed a significantly higher incidence in females 161 (AS, 164) per 100,000 person-years (CI, 142−181) compared with males 108 (AS, 110) per 100,000 person-years (CI, 97−119) ($P < .001$). The ratio of female to male annual average incidence was 1.5:1.

The incidence of CTD increased with increasing age, with the highest rates (307/100,000 person-years) occurring in the group aged over 70 years (Fig. 2).

In males, there was a steady increase in incidence with increasing age, reaching a maximum incidence of 317/100,000 person-years at 70 to 74 years. In females, there was a bimodal distribution, with a small peak between age 50 and 54 years of 289/100,000 person-years and a second higher peak at age 75 to 79 years of 331/100,000 person-years (Fig. 3).

The incidence of CTD was significantly higher in patients aged 65 years or greater compared with the group aged less than 65 years (261 vs 110/100,000 person-years; $P < .001$). There was no significant difference in incidence between men and women aged 65 years and above.

Nerve conduction study data were available for 1,104 patients (88%) in the later half of the study period, from 2005 to 2010. Mean age and sex proportions were similar to those of patients over whole study period. Median time from NCS to surgery was 160 days; 80% of patients had their CTD performed within 10 months of their NCS.

Mean NCS grade was 4.0 (CI, 3.9−4.0); more than 60% of patients in both sexes had an NCS grade at least of 4 (marked compression). Mean NCS grades increased with increasing age. Those aged 80 years and above had a mean NCS grade of 4.8 or higher. Patients aged 65 years or higher had a significantly higher mean NCS grade (4.4; CI, 4.3−4.5) than those aged less than 65 years (3.7; CI, 3.6−3.8; $P < .001$). Males tended to have more severe neurophysiological changes than did females at all ages, but this was statistically significant only for patients over age 65 years (males, 4.7 [CI, 4.5−4.8]; females, 4.2; CI, 4.1−4.4]; $P < .001$) (Fig. 4).

DISCUSSION

Carpal tunnel syndrome is traditionally thought to affect middle-aged women most commonly.[1,4,5,16] The incidence of CTS varies depending on which diagnostic definition is used as an end point. The prevalence has been reported to be as high as 5.8% in women and 0.6% in men.[16] A study of over half a million Korean patients with CTS noted that the highest incidence was in women aged 50 to 59 years, with an incidence of 1,811/100,000 person-years. However, only 115/100,000 person-years underwent

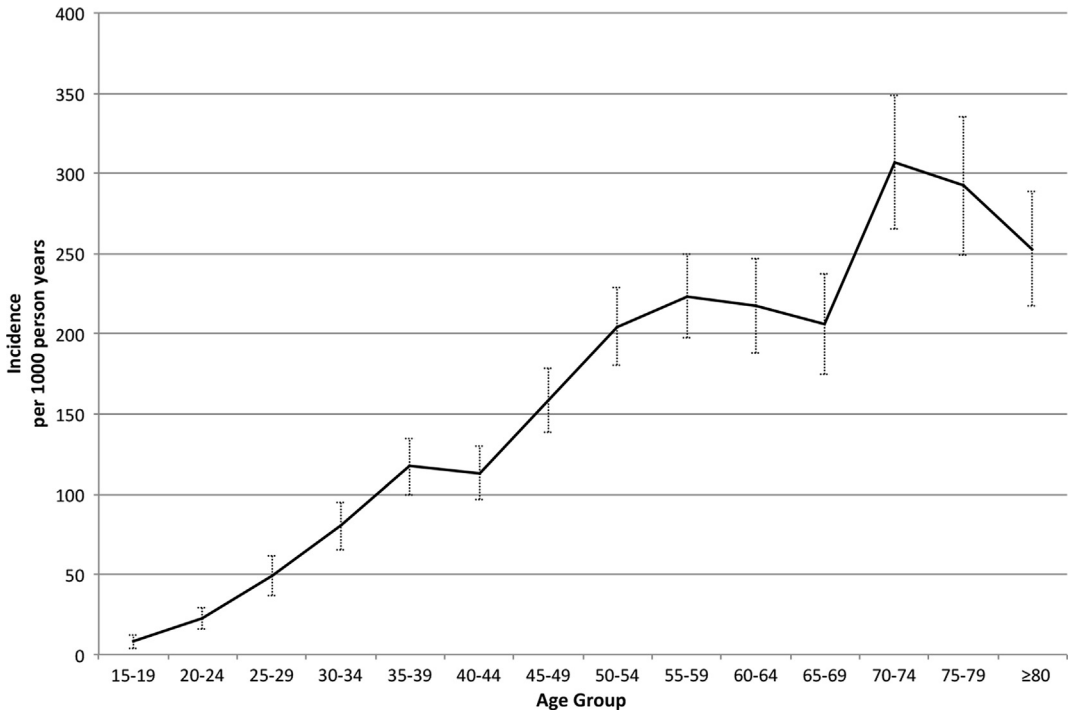

FIGURE 2: Age-specific annual average incidences of CTD.

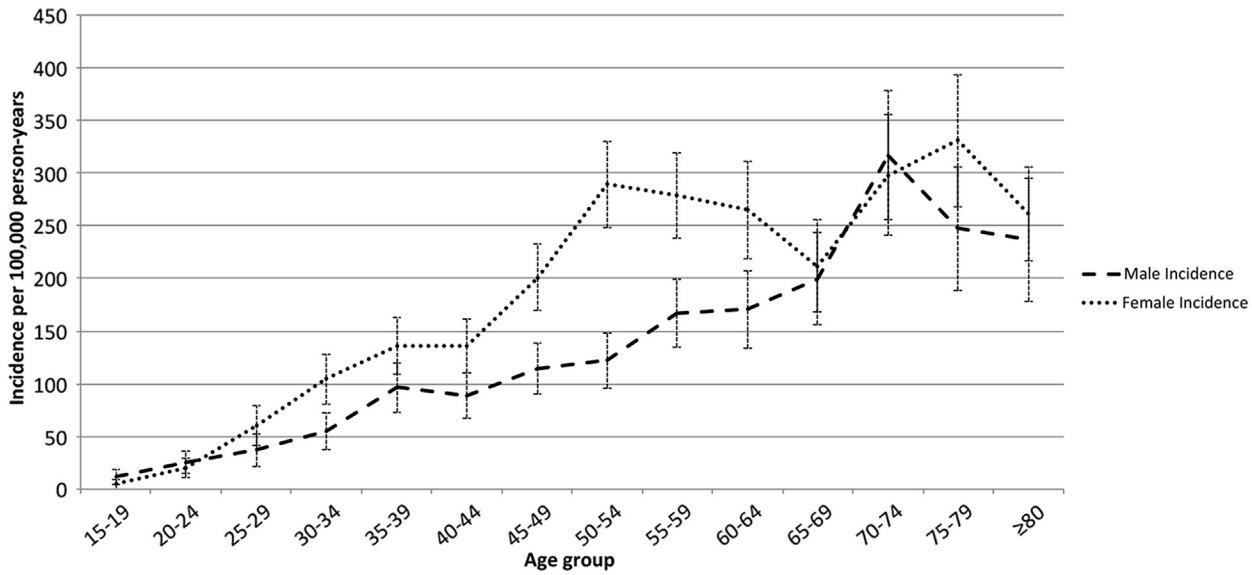

FIGURE 3: Sex- and age-specific annual average incidences of carpal tunnel release.

CTD.[17] The incidence for clinically and/or NCS-confirmed CTS ranges from 104 to 496/100,000 person-years.[17–24] The incidence is much lower when CTD is used as the end point: between 29 and 148/100,000 person-years[17,19,21,25–30] (Table 2).

In our study, we used CTD as the end point for disease. During the study period, there were few limitations to access to surgery, whether publicly or privately funded. We thought this improved our accuracy for a true diagnosis of CTS because it represented patients with both clinically and neurophysiologically confirmed CTS that was sufficiently symptomatic to require CTD.

Our CTD incidence of 137/100,000 person-years was similar to those of Keller et al[26] and Hanrahan et al,[27] 144 and 148, respectively, who also reported surgical rates. In women, our incidence (164/100,000 person-years) was similar to that of Mattioli et al[29] (166/100,000 person-years). However, their incidence

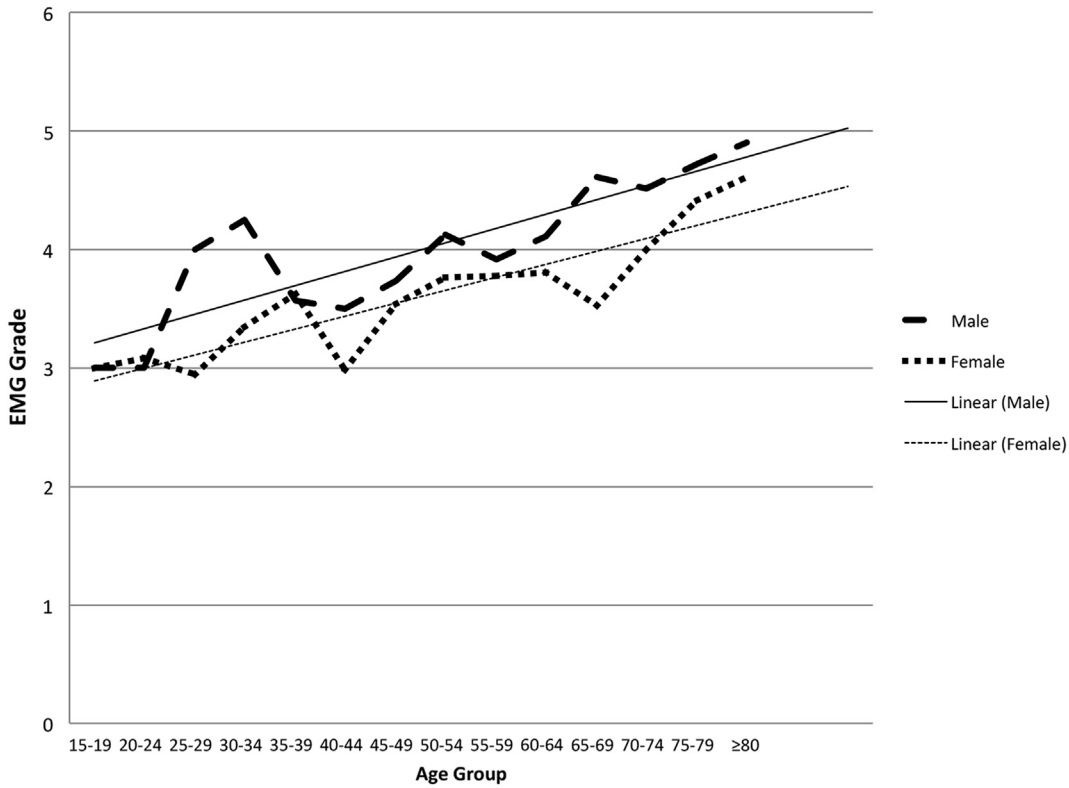

FIGURE 4: Mean NCS grades by age group.

in males was less than half of what was recorded in our study: 44 compared with 110/100,000 person-years.

A more recent study looking at the incidence of CTD in an ambulatory care setting in the United States[6] demonstrated a 38% increase in the number of procedures between 1996 and 2006. The overall incidence in males was 170/100,000 person-years, and in females was 360/100,000. The incidence rose with age in both sexes, with a peak of approximately 500/100,000 person-years in women aged over 50 years and a lower peak of almost 400/100,000 person-years in men aged 60 to 69 years. Although surgery was used as the end point, no data were presented on the diagnostic criteria used.[6] In contrast, Gelfman and Amadio[31] reported an incidence of 171/100,000 person-years in females and 96/100,000 person-years in males in their population, which is similar to our incidence.

In males, we found a general trend for the CTD incidence to increase until advanced age, with the highest incidence occurring in males aged 70 to 74 years (317/100,000 person-years). Other authors showed a similar single peak in the seventh or eighth decades.[17,24,25] However, Mondelli et al[20] showed a bimodal distribution in males that reached a peak in the group aged 50 to 59 years and a second higher peak in the group aged 70 to 79 years.

The incidence in females also gradually increased with age, but with a biphasic peak. The first peak (289/100,000 person-years) occurred in the group aged 50 to 54 years and a second higher peak occurred in the group aged 75 to 70 years (330/100,000 person-years). Gelfman et al[24] also had a bimodal distribution in their CTD incidence for women, with similar incidences in the groups aged 50 to 59 years and 70 to 79 years of 293 and 281 per 100,000 person-years, respectively. Liss et al. reported a higher peak in the 50-54 year age group of 368 and a lower peak at 75-79 year age group of 281 per 100,000 person-years.[25] Mondelli et al[20] showed a more classical distribution, with a single peak incidence in the group aged 50 to 59 years.

It is not clear why the incidence of surgically treated CTS should increase with age. Hormonal factors such as menopause, oophorectomy, pregnancy, and hormone replacement therapy are all associated with an increased risk of developing CTS in middle-aged women.[5,32] Most original descriptions of idiopathic CTS describe nonspecific tenosynovitis and synovial thickening or fibrosis leading to an increase in pressure within the carpal tunnel, which compresses the median nerve,.[1,33] Coexistent disease such as diabetes mellitus, inflammatory arthritis, obesity, hypertension, hypothyroidism, gout, vitamin B6 deficiency, uremia, and acromegaly all have known associations with CTS.[32,34] However, a

TABLE 2. Comparison of CTS Incidence Reported in the Literature

Study	Period	Region	Cases, n	Cases, Type	Incidence Rate/100,000 Person-Years			Ratio F/M
					Men	Women	Total	
Latinovic et al	2000	United Kingdom	28,706	Clinical	82	199	136	2.4
Roh et al	2005–2007	Korea	538,711	Clinical	276	712	496	2.6
Stevens et al	1961–1980	Rochester, United States	1,016	Clinical & NCS	52	149	105	2.9
Gelfman et al	1981–2005	Olmsted County, United States	10,069	Clinical & NCS	258	490	377	1.9
Bongers et al	1987	Netherlands	113	Clinical & NCS	60	190	130	3.1
Bland and Rudolfer	1991–1993	Huddersfield, United Kingdom	590	Clinical & NCS	35	62		1.8
Nordstrom et al	1991–1993	Wisconsin, United States (Marshfield Epidemiologic Study Area)	303	Clinical & NCS	316	362	339	1.1
Mondelli et al	1991–1998	Sienna	3,142	Clinical & NCS	139	506	276	3.6
Bland and Rudolfer	1992–2001	East Kent, United Kingdom	6,245	Clinical & NCS	60	121	104	2
Bongers et al	2001	Netherlands	672	Clinical & NCS	90	280	180	3.1
Roh et al	2005–2007	Korea	106,792	Clinical & NCS	58	138	98	2.4
Gelfman et al	1981–2005	Olmsted County, United States	2,823	Surgical	79	138	109	1.7
Liss et al	1988	Ontario, Canada	9,757	Surgical	67	138	103	2.1
Hanrahan et al	1990–1993	Wisconsin, United States		Surgical			148	
Keller et al	1993	Maine	1,677	Surgical			144	
Ebskov et al	1993–1994	Denmark	6,182	Surgical			61	
Rossignol et al	1994–1995	Montreal	238	Surgical	40	120	90	3
Mattioli et al	1997–2002	Tuscany	82,743	Surgical	44	166	106	3.8
Latinovic et al	2000	United Kingdom	889	Surgical	26.7	59.2		2.2
Roh et al	2005–2007	Korea	31,148	Surgical	8	49	29	5.8
English et al	2000–2010	Otago, New Zealand	2,309	Surgical	110	164	137	1.5

recent large-scale study from Taiwan showed a stronger association with these comorbidities in a younger population.[34] We believe that degenerative changes within the carpus may have a role.

Some authors have found that the incidence of CTS decreases with advanced age.[17,20] We only saw a decrease in the very elderly patients, over age 80 years. This late drop-off might be the result of patients either not presenting or not being diagnosed and referred.

In our region, we have excellent access to neurophysiological testing. The grading system we have developed has been adjusted for age to account for the natural slowing of conduction velocity through the median nerve with increasing age.[13,14,35] Our results showed a trend of increasing severity of the neurophysiological grade with increasing age, despite adjusting for age. A mean neurophysiological grade of at least 4 was seen in men aged older than 60 years and women aged older than 70 years. The most severe mean neurophysiological grade was seen in the group aged over 80 years, at 4.8. Bland and Rudolfer[21] noted a similar increase in median nerve severity in elderly

patients. Delay in diagnosis or referral may contribute to this. However, there are good outcomes from CTD in elderly patients in all but the most severe cases.[3,36] Therefore if the diagnosis is suspected in an elderly patient, it should be investigated promptly.

Previous studies have found that females have a lower mean neurophysiological grade across all age groups than men, as in this series. Women may perceive their health differently from men, and when they have symptoms of CTS, they may seek medical attention earlier. Men may be more tolerant, reporting fewer and or milder symptoms for the same neurophysiological grade.[35,37] Padua et al[37] also found that women usually have greater functional impairment for the same neurophysiological grade.

There are some limitations to our study. Because it is a retrospective review, we may have missed some patients. Not all patients had neurophysiological testing and we were not able to report outcomes of the surgery. However, we believe that the large numbers, consistent surgical indications, and widespread use of neurophysiological testing by a single neurophysiologist are strengths. There was no significant barrier to access neurophysiological testing or surgery during the study period and the intervention rates did not vary over time. The median delay from NCS to CTD of 160 days and the severity of NCS grade show that only refractory cases were treated surgically. This may explain why the incidences we report were significantly lower than those reported by the National Survey of Ambulatory Surgery.[6]

This study showed that a diagnosis of CTS should be carefully considered in both older men and women. Although the greatest numbers of CTD operations are on women aged 50 to 59 years, the highest incidence was in patients aged over 70 years. Over age 65 years there was no difference in incidence between men and women, and the neurophysiological changes were more severe. Awareness and appropriate funding decisions may ensure that these patients can benefit from a straightforward surgical intervention.

ACKNOWLEDGMENT

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The Outcome of Carpal Tunnel Decompression in Elderly Patients

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Purpose: To determine the outcomes of carpal tunnel decompression in elderly patients and whether outcomes can be predicted by the severity of presurgical nerve conduction study results.

Methods: We performed a retrospective study of all patients over 70 years of age who had elective carpal tunnel release at Dunedin Hospital between April 1999 and April 2002 with a minimum of 1-year follow-up evaluation. A grading system for presurgical nerve conduction studies was formulated that scored patients from 1 to 6 according to severity. Patients were evaluated by a mailed questionnaire (Symptom Severity Score) with follow-up telephone calls to nonresponders.

Results: Eighty-three carpal tunnel release procedures performed in 70 patients were included in the study. Eighty percent had marked to severe neurophysiologic changes (grades 4–6). The median postsurgical Symptom Severity Score was 1.3 (inter-quartile range, 1.1–1.7). Patients expressed satisfaction with the outcome of the surgery in 78 of 83 cases (94%). There was a significant relationship between presurgical nerve conduction grade and postsurgical Symptom Severity Score.

Conclusions: This study shows that elderly patients have low postsurgical symptom scores and express high levels of satisfaction after surgery for carpal tunnel syndrome. There was a significant relationship between severity of neurophysiologic abnormalities and a higher Symptom Severity Score after surgery. Severe abnormality, however, should not exclude elderly patients from surgery. (J Hand Surg 2005;30A:500–505. Copyright © 2005 by the American Society for Surgery of the Hand.)

Key words: Age, carpal tunnel syndrome, nerve conduction studies, outcome.

Carpal tunnel syndrome (CTS) is a common condition whose incidence increases with age.[1,2] Decompression of the median nerve in CTS is associated generally with a good result although the reported patient satisfaction rates vary widely. A number of factors have been reported to influence the outcome of surgery including gender, alcohol use, mental health status, attorney involvement, and presence of objective neurologic signs.[1,3,4] It has been suggested that increasing age also may have an independent adverse effect on outcome.[3,5] Tomaino and Weiser,[6] however, reported recently very good subjective results in a small group of patients over 70 years of age with advanced disease.

Presurgical nerve conduction studies (NCSs) are used to aid the diagnosis and assessment of median nerve integrity. The predictive value of NCSs, however, remains controversial.[3,7,8]

The main aim of this study was to investigate the subjective outcome of carpal tunnel decompression

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Table 1. Grading Carpal Tunnel Syndrome by Using Neurophysiologic Criteria

Grade	Palmar Latency	Sensory Conduction Velocity	Distal Motor Latency	Sensory Amplitude	Motor Amplitude
6 (Severe)	—	—	—	Absent	Absent
5 (Very marked)	—	—	—	>7.0 SD or absent	and >4.0 SD
4 (Marked)	—	>5.0 SD	or >5.0 SD	and >4.5 to <7.0 SD or absent	or >4.0 SD
3 (Moderate)	—	>4.0 to <5.0 SD	or >4.0 to <5.0 SD	and <4.5 SD	or <4.0 SD
2 (Mild)	>3.5 SD	or >3.0 to <4.0 SD	or >3.0 to <4.0 SD	and <3.0 SD	and <3.0 SD
1 (Borderline)	2.5–3.5 SD	and <3.0 SD	and <3.0 SD	and <3.0 SD	and <3.0 SD
0 (Normal)	All <2.5 SD	and <2.5SD	and <2.5 SD	and <2.5 SD	and <2.5 SD

NOTE: For conduction velocity and amplitudes SD refers to SDs less than the mean. For distal motor latencies and palmar latencies, SD refers to SDs greater than the mean.

(CTD) in patients over 70 years of age. A secondary aim was to determine whether patients with more severe presurgical neurophysiologic abnormalities had a worse subjective outcome.

Materials and Methods

Between April 1999 and April 2002, 108 elective CTDs in 93 patients over 70 years of age were performed in our unit. Inclusion criteria were as follows: patient over 70 years of age at time of surgery, elective surgery (emergency release for acute CTS was excluded), a minimum of 1 year of follow-up evaluation, neurophysiologically proven median nerve compression, and patient's ability to complete a standardized questionnaire. Of the 93 patients 8 had died, 5 had dementia and were unable to fill out the questionnaire, 9 patients had not had NCSs, and 1 patient with motor neurone disease was excluded. This gave 83 hands in 70 patients for review. There were 13 bilateral procedures (2 simultaneous), 24 left hands, and 33 right hands. Mean age was 78.5 years (range, 70–90 y) and 42 (55%) of the patients were women (46 hands).

It is the practice of our unit to request NCSs on the majority of patients with suspected CTS. All NCSs were performed by a single clinical neurophysiologist (P.K.T.) using standardized techniques.[9,10] These consisted of recording orthodromic median and ulnar sensory action potentials from middle and small finger stimulation, respectively, with measurements of peak-to-peak amplitude and conduction velocities calculated from both take-off and peak. If the median sensory conduction velocity and amplitude were normal or equivocal palmar studies were performed by stimulating the median nerve in the second and third interspaces and the ulnar nerve in the fourth interspace, 8 cm from the recording electrodes at the wrist. Median and ulnar motor conduction studies also were performed with stimulation at the wrist and elbow (median) or wrist only (ulnar) and recording from the lateral thenar eminence (median) and hypothenar eminence (ulnar). Measurements of distal motor latency and amplitude were made for both nerves and additionally forearm conduction velocity, dispersion, and amplitude change from elbow stimulation were calculated for the median nerve. All studies were performed with skin temperature at or above 33°C. Individual measurements were expressed as the number of SDs from the mean using age and body size variables calculated from a normal population.[9,10] In our unit needle electromyography is not performed routinely on patients with suspected CTS because this does not increase the diagnostic sensitivity of the neurophysiologic investigation.[11]

NCS results were graded as shown in Table 1. This is an amplitude-weighted grading system that we believe matches median nerve pathophysiology most accurately to patient symptoms.

Carpal tunnel decompressions were performed as day cases under local anesthesia by either a registrar or consultant. The transverse carpal ligament was divided under direct vision. No surgeon in this unit currently performs endoscopic release. The mean time from NCSs to surgery was 6.3 months (range, 0–74 mo) and the mean time from surgery to follow-up evaluation was 29.2 months (range, 12–49 mo).

The Symptom Severity Questionnaire of Levine et al[12] was mailed to all patients. This validated, condition-specific questionnaire has 11 questions based on the frequency, duration, and severity of pain, numbness, parasthesia, and weakness and is repro-

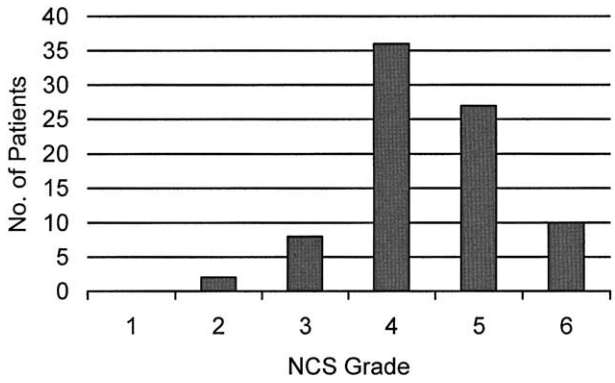

Figure 1. Distribution of presurgical neurophysiologic grades.

ducible, sensitive to clinical change, and internally consistent. Each question is scored from 1 to 5, where 1 is normal or no symptoms and 5 is the worst score. A mean score then is calculated for each patient. The patients also were asked if they were satisfied with the result of surgery and would have the surgery again. Nonresponders and incomplete or incorrectly answered questionnaires were followed-up by telephone by an independent reviewer.

Statistical analysis was performed using statistical software (Stata 8.1 package; Stata Corp LP, College Station, TX). Relationships were calculated by using linear regression analysis clustered to patient to allow for lack of independence arising from patients who had bilateral surgery.

Results

The distribution of presurgical NCS grades is shown in Figure 1. Eighty percent had marked to severe neurophysiologic changes (grades 4–6).

The median postsurgical Symptom Severity Score for all 83 hands was 1.3 (interquartile range, 1.1–1.7) and the mean was 1.57 (SD, 0.48) The score is calculated as an average of the responses for the 11 questions. A score of 1 indicates no symptoms and a score of 5 indicates severe symptoms. The Symptom Severity Score was less than 2.0 (none to mild symptoms) in 68 hands (82%), between 2.0 and 2.7 (mild to moderate symptoms) in 9 hands (11%), and between 3.0 and 4.2 (moderate to severe symptoms) in 6 hands (7%) (Fig. 2). All 6 hands with a postsurgical Symptom Severity Score greater than 3 had a presurgical NCS result of grade 4 or greater. Patients generally expressed satisfaction with the result of the surgery and indicated they would have the surgery again in 78 of 83 cases (94%). Only 2 of the 6 patients with Symptom Severity Scores greater than 3.0 were dissatisfied. The other 3 dissatisfied patients had scores of 1.8 to 1.9.

We divided the Symptom Severity Score questions into 3 groups: 5 questions (1–5) were concerned with pain, 4 questions (6, 8–10) with numbness and tingling, and 2 questions (7, 11) with function and strength. This showed little difference in outcomes with regard to pain or sensory symptoms and a slightly worse outcome for function (Table 2).

The second aim of this study was to determine whether there were poorer outcomes in patients with more severe presurgical neurophysiologic grade. A linear regression analysis with robust standard errors clustered to patient was performed because it is not possible to adjust with a correlation for the lack of independence arising from patients having bilateral surgery. There was a significant relationship between

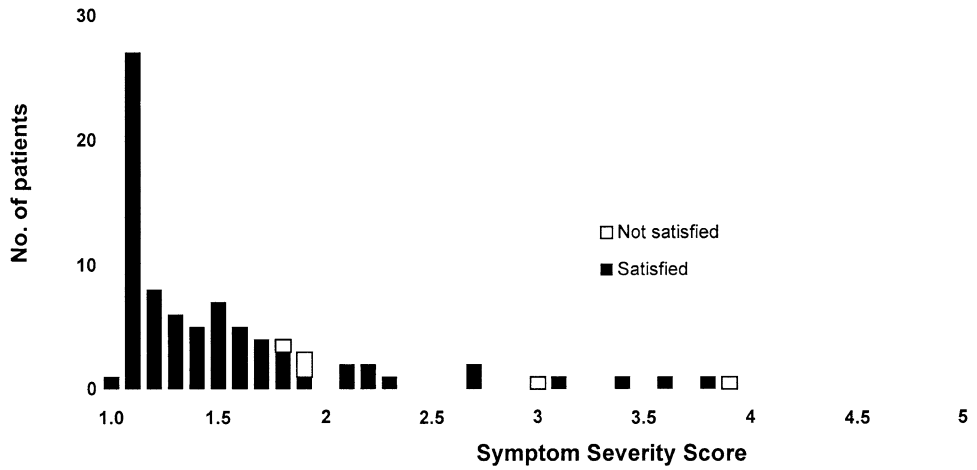

Figure 2. Distribution of postsurgical Symptom Severity Scores including patient satisfaction with surgery (1 = no symptoms, 5 = worst symptoms).

Table 2. Postsurgical Symptom Severity Scores by Question Type and Relationship With Presurgical NCS Grade

	Pain Questions	Sensory Questions	Function Questions	Total Symptom Severity Score
Median score	1.2	1.25	1.5	1.3
Interquartile range	1.2–1.8	1.0–1.6	1.0–2.5	1.1–1.7
Mean score	1.58	1.44	1.8	1.57
Regression coefficient with NCS grade (SE)	0.393 (0.354)	0.555 (0.261)	0.620 (0.217)	0.143 (0.0678)
p value	.271	.037*	.006*	.039*

SE, standard error.
*p value significant.

nerve conduction grade and Symptom Severity Score ($p = .0391$) (Fig. 3) and scores from the questions relating to function ($p = .006$) and sensory symptoms ($p = .037$) but none with the questions concerning pain ($p = .271$) (Table 2). Despite this relationship a full range of scores from 1.1 to 3.8 were seen in the most severe grades and 34 of the 37 patients with the most severe changes (grades 5, 6) were satisfied with the outcome of their surgery.

There was no relationship between postsurgical Symptom Severity Score and time from NCS to surgery or duration of follow-up evaluation.

Discussion

Open CTD in appropriately selected patients is usually an effective procedure with both objective and subjective improvements in symptoms and NCS results. Many studies show complete relief or marked improvement in symptoms in 80% to 100% of patients.[7,8,13,14] Bland[3] commented that more widely based studies had lower satisfaction rates (70% to 90%). His large study showed success in 74% but 11.4% were worse after surgery. These figures are similar to those of Porter et al[5] who had 77% satisfied and 11.5% dissatisfied after surgery. Katz et al[4] reported 66% of patients completely satisfied after surgery.

In most centers neurophysiologic studies play an important role in the diagnosis and management of CTS.[15] Part of this role is to provide information about the degree of pathologic change in the median nerve at the wrist. Various grading scales have been proposed that are based largely on conduction velocity criteria plus a presence/absence criterion for motor and sensory action potentials.[3,7,16] We believe, however, that changes to motor and sensory amplitudes are more likely to reflect the degree of clinically relevant pathology (axonal loss and conduction block) in the median nerve and have developed a grading scale that incorporates amplitude criteria. The more severe grades in all grading systems feature neurophysiologic changes that mainly reflect axonal loss. Patients occupying these grades, therefore, may be expected to require longer recovery periods or may have incomplete recovery. Although the retrospective nature of our study did not allow us to determine time to recovery accurately our results did show that the more severe grades were associated with less complete recovery and persistence of symptoms. This is consistent with the findings of Bland[3] who reported less successful outcome from surgery for more severe grades in a non–age-selected population of CTS patients. Despite these less successful outcomes the majority of our patients reported satisfaction from surgery even when their nerves had shown marked presurgical pathology. The short regrowth distances for axonal regeneration from the carpal tunnel to the skin and muscles of the hand are likely to be an important factor in facilitating this recovery. Another important factor, however, may be the expectation regarding surgical outcome that patients with more severe neurophysiologic changes have been given before surgery.

Increasing age has been reported to lead to poorer results in some series[3,5] but not others.[4,14] Porter[5] showed that patients over 60 years of age had significantly less improvement in symptom severity and functional status and only 66% were satisfied after surgery compared with 87% satisfaction in patients under 60 years of age. Bland[3] found that older patients had a poorer prognosis independent of other factors but the effect was weak and did not preclude good outcomes. We found the satisfaction rate after surgery to be very high (94%). The median Symptom Severity Score of 1.3 and mean of 1.58 in our patients compares favorably with published mean

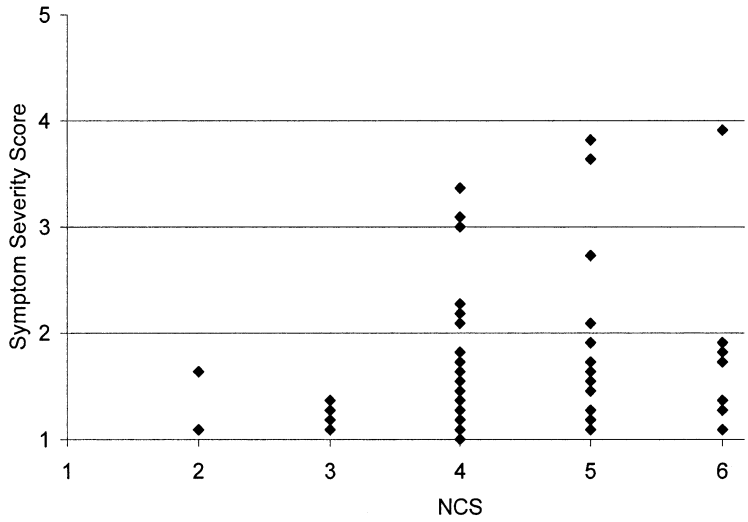

Figure 3. Scatter plot showing relationship between Symptom Severity Score and presurgical NCS scores (Linear regression coefficient, 0.143; p = .039).

scores of 1.3 to 1.9 from other studies using this instrument.[5,12,14,17] Only 6 patients in our study had scores of 3.0 or higher, indicating moderate to severe residual symptoms. Four of these patients expressed satisfaction with surgery; therefore they may have had an improvement from their presurgical status despite residual symptoms. Our results confirm those of Tomaino and Weiser[6] who showed a high rate of satisfaction in a group of 13 patients over 70 years of age who were shown to have severe presurgical neurophysiologic abnormalities. If a patient with neurophysiologically confirmed median nerve compression has no improvement at all after surgery it may be caused by an inadequate decompression rather than irreversible nerve damage.

A problem in comparing the results of surgery is the number of different outcome measures used to report results.[18] Both Amadio et al[19] and Katz et al[4] have found that subjective outcome scores were more sensitive to change than traditional physical measures and that physical examination had little usefulness for predicting postsurgical functional limitations, symptoms, or satisfaction. Improvements have been reported in general outcomes scores such as the Arthritis Impact Measurement Scale and the Short-Form 36; however, these changes were not as great as those seen with the condition-specific Symptom Severity Score.[19] This instrument also has been the most widely reported and therefore the one we chose. Because of the retrospective nature of our study a postsurgical general outcome score would have had little relevance and therefore was not included. A weakness in this retrospective study is the lack of presurgical Symptom Severity Scores, which precludes an accurate assessment of the surgical benefit. The postsurgical score, however, does allow comparison with the results from other series. The low scores found translate directly into absent or mild symptoms in 82% of patients. We were concerned that the relative weighting of pain symptoms (5 questions) over neurologic symptoms may generate error in an elderly population that is more likely to be affected by comorbidities such as osteoarthritis. This may explain why preoperative Symptom Severity Scores have not been shown previously to correlate with outcome.[8] Postsurgical Symptom Severity Scores, however, should pick up poor results caused by complications of surgery such as neuropathic pain, scar tenderness, and pillar pain. One of our patients who expressed satisfaction with surgery but had a high Symptom Severity Score indicated that she thought her rheumatoid arthritis may have caused her pain and functional deficit rather than CTS. Although we saw a significant relationship between the presurgical NCS grade and postsurgical total Symptom Severity Score and the sensory and functional components there was no relationship with pain scores.

We have shown that high satisfaction rates and good outcomes can be expected in CTS surgery in the elderly even when neurophysiologic tests show marked abnormalities. The postsurgical Symptom Severity Scores in our group compare favorably with published scores in younger patients. Severe presurgical neurophysiologic abnormalities should not preclude elderly patients from surgery because although

they tend to have higher Symptom Severity Scores before surgery than the milder grades they still are likely to be satisfied with surgery, particularly if realistic expectations about surgical outcome are established at the outset.

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Chapter 3

Prevention: Neonatal Hip screening.

Any reduction in patients requiring *acute* orthopaedic surgery will have an effect on our ability to maintain elective volumes. The use of bisphosphonates is recommended for the treatment of osteoporosis and has been associated with a reduction in fragility fractures including hip fractures. Safety programmes to reduce road trauma and neuromuscular training to reduce sports injuries all have a role to play in prevention of musculoskeletal injury. In contrast, there is little that can be done to prevent many conditions that may require elective orthopaedic surgery. Advances in the medical management of rheumatoid arthritis have reduced the surgical burden significantly. However, the high volume/ high cost procedures such as total hip and knee replacement and spinal surgery are typically caused by degenerative osteoarthritis for which there is little effective medical treatment. Osteoarthritis is the primary diagnosis in 87% of hip replacements and 95% of knee replacements.[1] Lifestyle changes such as weight loss may have an effect if implemented early enough but we are likely to see a large increase in demand due to the current obesity epidemic.

One area, which has made a small impact, is neonatal screening for congenital dislocation of the hip (CDH), now better known as developmental dysplasia of the hip (DDH). DDH is given as the principal diagnosis in 2.2% of THRs in the New Zealand Joint Registry. However, it is likely that acetabular dysplasia of lesser degree is the underlying cause of many patients with secondary osteoarthritis. [2,3] The clinical tests of Barlow and Ortolani have been effective in detecting hip instability at birth. It is now very uncommon to see patients with high riding dislocated hips in adulthood. We have provided a clinical screening service by orthopaedic surgeons for many years. We have also used ultrasound scans for both screening and management of neonatal hip instability.

The first paper in this chapter '*The diagnosis and management of neonatal hip instability: Results of a clinical and targeted ultrasound screening program'* reviews the results of our clinical screening and targeted ultrasound program that has been in place since 1989. The second paper '*Ultrasound measurements in the management of unstable hips treated with the Pavlik harness: reliability and correlation with outcome'* investigates various ultrasound measurements and their role in the management of unstable hips during treatment in a Pavlik harness. The third paper '*Late presenting dislocation of sonographically stable hips'*reports on a series of babies with hips that were stable on ultrasound screening that subsequently dislocated. Although some of the hips were unstable at birth, all had stabilised by the time of their ultrasound at 2-6 weeks. This helps confirm that hip dysplasia forms a spectrum of disease and is important from a medico-legal perspective.

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The Diagnosis and Management of Neonatal Hip Instability

Results of a Clinical and Targeted Ultrasound Screening Program

Andrew G. S. Vane, MBBS, David P. Gwynne Jones, FRACS (Orth), John D. Dunbar, FRACS (Orth), and Jean-Claude Theis, FRACS (Orth)

Abstract: This article reports the results of a neonatal hip screening program comprising clinical screening and targeted ultrasound performed by orthopaedic surgeons. Over 7 years, from 1995 to 2001, there were 15,397 live births in the authors' region. Seven hundred thirty-three babies (4.8% of births) were referred for hip ultrasound: 80% for risk factors and 20% for instability. Eighty-three babies (5.4/1,000) were splinted in a Pavlik harness. Three of these subsequently required surgery (1.9/1,000). Ten patients (0.65/1000) presented with hip dislocation after 12 weeks of age, nine of whom required open or closed reduction (0.56/1,000). From 1978 to 1985, when neonatal pediatricians clinically screened all babies, 18 babies presented late from 13,707 births (1.3/1000). Since the introduction of orthopaedic screening and targeted ultrasound, there has been a significant reduction in late diagnosis in the authors' institution.

Key Words: hip dislocation, congenital, ultrasonography, screening

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It is generally accepted that newborn babies should be screened for hip instability by clinical examination using the Barlow and Ortolani tests. In the best reported series, the incidence of established dislocation of the hips was reduced to 0.1 per 1,000[1] from a rate prior to screening programs of 1.55 per 1,000.[2] Although not all programs have been able to achieve these results, the ideal practice remains clinical examination on at least two or three occasions in the first 6 weeks of life.[3] Ultrasound of pediatric hips was introduced approximately 20 years ago to help in the diagnosis of neonatal hip instability. While routine ultrasound of all newborns has been advocated, it has not been shown to be practical or cost-effective and is not recommended by the American Academy of Pediatrics.[4] Targeted programs with screening of high-risk infants have not been shown to reduce the late presentation of developmental dysplasia of the hip (DDH) below that of the best clinical series.[5–8] This may be because up to 69% of babies with late-diagnosed DDH have no risk factors.[9] We have used clinical and targeted ultrasound screening by an orthopaedic surgeon since 1989 and report our experience since 1995.

PATIENTS AND METHODS

Since 1989 our screening program has consisted of in-hospital examination of newborn babies by a pediatrician and one of three consultant orthopaedic surgeons. Babies discharged early are seen back either on the ward or at an orthopaedic clinic. Babies born in peripheral centers are seen by visiting orthopaedic surgeons. Indications for ultrasound are clinical instability, major risk factors (breech, family history, foot deformity, torticollis) or an equivocal clinical examination. The scan is performed at 2 to 4 weeks of age, at a dedicated clinic, by an orthopaedic surgeon and an experienced sonographer. Coronal and transverse scans and stress views are performed as described by Graf,[10] Morin et al,[11] and Clarke et al.[12] Treatment with a Pavlik harness is instigated at birth if the hip is dislocated or grossly unstable or at the time of the ultrasound if there is persisting instability or acetabular dysplasia. Any treated babies are followed by ultrasound and the harness is removed when the hip is stable clinically and sonographically and the head coverage is at least 40%. If the hips fail to stabilize or develop normally, then further treatment (abduction bracing, closed reduction, or open reduction) is performed as required. Radiographs are performed in preference to ultrasound after the age of 4 months.

Records of all births at our institution from January 1995 to December 2001 were obtained and checked with official birth statistics. All babies subsequently seen in the ultrasound clinic were identified from radiology department records and hospital notes. We defined late-presenting DDH as greater than 12 weeks of age at diagnosis.[5,13] Late-presenting cases were identified from our surgical audit for the period from 1989. Orthopaedic surgeons throughout New Zealand with an interest in pediatrics were surveyed to see whether any babies born in our region had subsequently presented elsewhere with a late dislocation.

An historical comparison was made with the period 1978 to 1985. Details of all cases of late-treated and severe DDH had been identified from a previous study and compared with birth rates (Dickson N, personal communication). Statistical comparison was performed using chi-square analysis with Yates correction.

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RESULTS

Over the period 1995 to 2001 there were 15,397 live births in Otago. An audit of the clinical screening diaries revealed that an average of 81% of babies born at our institution were clinically screened by the orthopaedic service. This is a minimum figure, as babies attending pediatric orthopaedic clinics and peripheral clinics come on an informal basis.

Seven hundred thirty-three babies were referred for ultrasound scan (4.8% of all babies). Of these, 593 (80%) were referred for risk factors and had a normal clinical examination and normal ultrasound scan and were discharged. One hundred forty babies (9/1,000 live births) were referred for varying degrees of instability. Fifty-seven with minor clinical instability or equivocal findings were followed without treatment until a normal examination and a normal ultrasound were obtained. Eighty-three babies with unstable hips were treated in a Pavlik harness: 77 after the initial clinical examination (mean 1.8 days old), 5 after the first ultrasound scan (mean 10.6 days), and one after a second scan at 59 days. This gave a splintage rate of 5.4 per 1,000. Eight of 83 splinted babies failed to stabilize after 6 weeks of splintage. Five responded to extended harness treatment or abduction bracing, but three (babies 1–3, Table 1) required early closed reduction and hip spica application after a period out of the harness. One of these (baby 2) subsequently required open reduction and bilateral femoral osteotomies.

Ten cases (seven girls, three boys) presented after 12 weeks of age, giving a late presentation rate of 0.65 per 1,000. The average age was 12 months (range 12 weeks to 26 months) at diagnosis. Nine had been born at our institution and one at another hospital. There were three cases of bilateral dislocation, two right and four left dislocations, and one dysplastic acetabulum. Six had been examined by an orthopaedic surgeon at birth with no instability detected; one of these (patient 8) also had two ultrasound scans with no instability seen. Three babies had missed orthopaedic screening: all were premature births. One baby (patient 4) had been diagnosed with instability at birth at another center and treated with a Pavlik harness. An ultrasound and clinical examination at 37 days showed no persisting instability, and treatment was discontinued. A pelvic radiograph at 6 months showed bilateral dislocations. Eight babies underwent closed reduction, one had bilateral open reductions and subsequent femoral osteotomies, and one baby stabilized after treatment with an abduction brace for 8 weeks. Two children treated with closed reduction have subsequently required late Salter osteotomies for persisting acetabular dysplasia. This gives a surgical rate of 0.58 per 1,000 for late presentation and 0.19 per 1,000 for failure of Pavlik harness treatment, and a total surgical rate of 0.77 per 1,000 over the 7-year period.

Historical Comparison

From 1978 to 1985, experienced neonatal pediatricians examined the hips of all babies born at our institution in addition to the routine neonatal examination. An audit of hip diaries in 1983–84 revealed that 42 babies out of 2,479

TABLE 1. Details of Patients Treated Surgically

Pt. No.	Sex	Risk Factors	Ortho Exam at Birth	Ultrasound	When Diagnosed	Side	Pavlik Harness	Closed/Open Reduction	Adductor Tenotomy	Osteotomy
1	F	None	Yes Unstable	Yes	Day 1	R	Yes	Closed	No	No
2	F	First born	Yes Unstable	Yes	Day 1	L	Yes	Closed (failed) then open	Yes	No
3	F	First born C section	Yes Unstable	Yes	Day 1	Bilat	Yes	Closed	Yes	No
4	F	None	Yes Unstable	Yes 35 days	6/12	Bilat dislocations	Yes	Closed	Yes	No
5	F	Breech, premature, 30 wks	No	No	7 months	R acetabular dysplasia	No	Abduction brace	No	No
6	F	Premature 35 wks	No	No	26/12	Bilat	No	Open but failed	Yes	Femoral shortening 30 months
7	M	Renal anomalies	Yes Stable	No	19/12	R	No	Closed	Yes	Salter 4 yrs
8	F	Breech	Yes Stable	Yes 31 days, 45 days	23/12	R	No	Closed	Yes	Salter 5 yrs
9	M	No	Yes Stable	No	11/12	L	No	Closed	Yes	No
10	F	No	Yes Stable	No	11/12	L	No	Closed	Yes	No
11	F	Postural talipes	Yes Stable	No	5/12	L	No	Closed	No	No
12	F	Family history	Yes Stable	No	9/12	L	No	Closed	No	No
13	M	Premature, renal anomalies	No	No	3/12	Bilat	No	Closed	No	No

examined were referred to an orthopaedic surgeon for clinical instability (17/1,000). During the 8-year period, out of 13,707 births, there were 18 dislocations that presented after 18 weeks, giving a late presentation rate of 1.3 per 1,000. Orthopaedic surgeons assumed responsibility for screening and introduced ultrasound in 1989. In the period 1989 to 2001 there were 14 late-presenting cases (after 12 weeks) out of 30,089 live births (0.47/1,000). This reduction is significant ($P = 0.0038$).

DISCUSSION

A consultant orthopaedic surgeon examines at least 81% of all babies born at our institution, representing 66% of total births in our region. We believe that this can be improved by implementing a formal recall system and endeavoring to include the neonatal intensive care unit (NICU) on rounds. Some babies are discharged from NICU directly home, and three babies who presented late, having missed orthopaedic screening, were premature.

In populations with clinical screening programs, the detection rate of hip instability ranges from 5 to 34 per 1,000.[14] Our rate of 9 per 1,000 compares with the American Academy of Pediatrics baseline estimate of DDH of 11.5 per 1,000.[4] Hadlow diagnosed instability in 32 per 1,000, half of which stabilized without treatment.[1] Historically, in our institution, the neonatal pediatricians diagnosed instability in 17 per 1,000.

Bjerkreim et al found that 77% of 799 babies with late DDH had had a documented normal clinical hip examination at birth.[15] In our series 7 of 10 babies presenting late with DDH had been examined at birth or shortly after by an orthopaedic surgeon. In two cases ultrasound examination had also shown stable hips. This supports the concept of developmental dysplasia.

It was hoped that the use of ultrasound would significantly increase the sensitivity of neonatal hip screening. General routine ultrasound screening of all babies has been advocated but is impracticable and still may not reduce the incidence of late presentation.[4,16] It detects minor degrees of abnormality, which may lead to treatment rates as high as 34 per 1,000.[7] Marks et al showed that 90% of these ultrasound abnormalities resolve by 9 weeks but found five babies (0.57/1,000) with persisting ultrasound abnormalities who had no risk factors or instability and who would not have otherwise been identified by clinical examination or targeted ultrasound screening.[17] Other targeted ultrasound programs have scan rates ranging from 1.4% to 7% of live births.[5,6,9,18] Our average scan rate, currently 4.8% of all babies, is decreasing, as we are scanning fewer babies with minor risk factors alone. In this study, no baby scanned for risk factors was subsequently treated. This is probably because clinical instability was detected by an orthopaedic surgeon in those babies with risk factors who required treatment. However, three of the babies who presented late had risk factors but were not referred for scan. One was not screened, but the other two should have been scanned as per protocol. We therefore still recommend targeted ultrasound for patients with any suggestion of instability or an equivocal examination, a positive family history, breech position, foot deformity, torticollis, oligohydramnios, or combinations of these, including female sex and birth rank.

We treat at birth if the hip is dislocated or Barlow or Ortolani positive. By delaying splintage in cases of minor instability until a scan and re-examination at 2 to 4 weeks, our treatment rate is 5.4 per 1,000. This is similar to the rates of 3.1 to 6 per 1,000 in other series where ultrasound is used,[5,6,13,19,20] while Hadlow treated 16 per 1,000 in his study using clinical screening alone.[1] Ultrasound influenced us to commence treatment in six babies (0.39/1,000)—in five cases after the first scan showed acetabular dysplasia and dynamic instability and in one after the second scan at 6 weeks showed persisting instability. In retrospect, two other patients had persisting borderline ultrasound abnormalities at 5 to 6 weeks, although the hips were stable clinically and ultrasonographically. Boeree and Clarke found that ultrasound influenced them to treat in 0.63 per 1,000.[5]

The babies we treated in a Pavlik harness remained in harness for an average of 41 days until they were stable clinically and on ultrasound had at least 40% head coverage. A similar length of treatment time (6.3 weeks) was reported by Sochart and Paton,[13] who also use ultrasound to aid in diagnosis and to monitor treatment. Hangen et al[21] found a significantly shorter treatment time in babies with DDH who were followed by serial ultrasound than those that did not have ultrasound. Reducing the time splinted may also reduce the risk of avascular necrosis.[13] We believe that monitoring the treatment of DDH with ultrasound is valuable as it allows us to tailor the treatment time both by decreasing the duration of splintage in hips that have stabilized and have normal anatomy and by identifying treatment failure early.

It has been shown that careful examination of neonatal hips by experienced personnel can significantly decrease the rate of late-presenting hip dislocation.[1,22] Barlow suggested the true rate of neonatal hip dislocation in unscreened populations to be 1.55 per 1,000 births.[2] Our rate of late-presenting hip dislocation of 0.65 per 1,000 for this 7-year study period, and 0.47 per 1,000 since 1989, lies within the range of 0 to 0.9 per 1,000 reported by centers with established neonatal hip screening programs.[1,5,6,9,13,19] It is now over 2 years since the last babies were born, and therefore it is unlikely that further late cases will present.

Before screening programs were implemented, the rate of surgery approximately equaled the rate of dislocation at 1.63 per 1,000 live births.[5] Others have reported surgical rates of 2.1 per 1,000.[23] Our combined surgical rate of 0.77 per 1,000 includes all closed reductions, with or without adductor tenotomy, as well as open reduction and femoral or pelvic osteotomy to avoid surgeon preference bias when comparing figures. Boeree and Clarke[5] reported a surgical rate including adductor tenotomies of 0.4 per 1,000, while Paton et al[6] reported a rate of 0.87 per 1,000 for open reduction and/or pelvic or femoral osteotomy.

We have seen a significant reduction in late presentation rates of DDH at our institution since orthopaedic surgeons have assumed responsibility for the screening program. It is possible that the reduction may be due to improved accuracy of the clinical screening when performed by an orthopaedic surgeon compared with an experienced pediatrician. However, we find ultrasound to be an essential part of the screening program. Boeree and Clarke also noted a significant reduction

in surgical treatment of DDH after the introduction of their program, which included targeted ultrasound.[5] Targeted ultrasound screening may not have reduced the late presentation rate below that of the best clinical series, but it is still better than many clinical series.[23]

We recommend the use of ultrasound as an adjunct to clinical screening when performed with an orthopaedic surgeon in attendance. We also find it is useful in monitoring the treatment of DDH, preventing overtreatment, and detecting failure of treatment early.

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Ultrasound Measurements in the Management of Unstable Hips Treated With the Pavlik Harness

Reliability and Correlation With Outcome

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Abstract: The purposes of this study were to determine the interobserver and intraobserver reliability of ultrasound measurements in unstable neonatal hips treated with the Pavlik harness and to determine whether ultrasound measurements correlate with radiological outcome at 6 months. Sixty-four babies treated from birth with the Pavlik harness for neonatal hip instability were scanned at 2 and 6 weeks. The α and β angles of Graf, the combined (*H*) angle of Hosny, and the femoral head coverage (FHC) were measured by 3 observers and remeasured by each observer on a minimum of 50 scans. From 248 scans, 792 sets of measurements were made. Hips were categorized as normal, abnormal, or borderline for each parameter; and interobserver and intraobserver repeatability coefficients and Kappa values were calculated. The α angle had the smallest interobserver range (17 degrees), the *H* angle range was 21 degrees, and the β angle 28 degrees. Kappa values were best for the FHC and β angle (0.66–0.8). The mean acetabular index (AI) of all hips at 6 months was 26 degrees (SD, 4.9). The AI was 30 degrees or greater in 24 hips (18 babies) despite prolonged splintage in 9 hips (6 babies). A stepwise linear regression analysis showed that the FHC at 6 weeks was predictive of AI at 6 months (regression coefficient −0.27; 95% confidence interval −0.42 to −0.12; $P < 0.001$). We recommend the FHC as being reproducible, useful, and predictive of outcome in neonatal hips treated for instability.

Key Words: developmental dysplasia of hip, ultrasound

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Ultrasound has been widely used to aid in the diagnosis and the management of neonatal hip instability. It is helpful in determining whether a hip is dislocated or unstable and whether it is reduced in a Pavlik harness.[1–4] It is important that quantitative measures of the neonatal hip should be reliable and reproducible to aid in management decisions. Ideally, ultrasound measurements should also be predictive of the subsequent outcome. Static measurements of the neonatal hip include the α and β angles of Graf,[5] and the femoral head coverage (FHC) as determined by the *d*/*D* ratio of Morin et al.[6] The α angle and FHC have generally been found the most reliable.[7–10] However, they have limited value in predicting the subsequent outcome of a hip, with persisting instability being the most useful indicator.[11] Many of these studies have been using ultrasound as a screening tool and have also included a high proportion of normal hips. Recently, Hosny et al[12] introduced a new combined angle that correlated with the α angle; and they found it to be the most reproducible.

The purpose of this study was to compare the interobserver and intraobserver reliability of Graf's angular measurements (α and β angles), the combined angle of Hosny (*H* angle), and the FHC in a group of babies treated with a Pavlik harness from birth for clinical instability. Secondly, we investigated whether any of the ultrasound measurements at 2 and 6 weeks were predictive of radiographic outcome at 6 months.

METHODS

We have previously described our screening and management of neonates with developmental dysplasia of the hip (DDH).[13] Since 1989, our screening program has consisted of in-hospital examination of all newborn babies by 1 of 3 consultant orthopaedic surgeons. We treat most babies with definite clinical instability (Barlow or Ortolani positive hips) from birth with a Pavlik harness for 6 weeks. Babies with clinical instability, an equivocal examination, or major risk factors (breech presentation, family history, foot deformity, torticollis, etc) are referred for ultrasound scan. Our treatment rate is approximately 5.4/1000.[13] Ultrasounds are performed by an experienced sonographer with 1 of 2 pediatric orthopaedic surgeons in attendance at 2 and 6 weeks of age if the hip is unstable. Coronal and transverse scans and stress views are performed as described by Graf,[5] Morin et al,[6] and Clarke et al.[1] Treatment decisions are based on clinical and sonographic stability, FHC, and acetabular morphology. We have not formally measured angles or the FHC. Hips that have not stabilized by 6 weeks or have persisting dysplasia remain in a Pavlik harness or an abduction brace. Splintage is discontinued when the hip is stable and the acetabulum appears to be developing normally.

Three observers (1 orthopaedic surgeon and 2 orthopaedic residents) blinded to the outcome reviewed the sonograms performed at 2 and 6 weeks and the 6-month radiographs of a consecutive series of 64 babies treated from

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birth for clinical hip instability. There were 55 girls and 9 boys. Nine babies (all girls) required prolonged splintage with an abduction brace. Four of these babies (6 hips) subsequently required closed reduction. There were no significant complications from the Pavlik harness treatment.

The α, β, and *H* angles of both hips were measured using a standard goniometer. A wax pencil was used so that marks were completely removed from the sonogram before second measurements were made. The FHC was calculated by measuring the *d*/*D* ratio as described by Morin et al[6] and multiplying by 100 to give a percentage figure. The acetabular index (AI) of Sharp[14] was measured from the 6-month radiograph. An AI greater than 30 degrees was defined as definite dysplasia, as this equates to approximately greater than 2 standard deviations above normal at this age, and mild dysplasia if greater than 25 degrees.[15]

Each observer then repeated the measurements on a minimum of 50 scans on a separate occasion.

Statistical Analysis

Interobserver and intraobserver repeatability coefficients were calculated using 95% confidence interval (CI) of the differences between repeated measurements.[16] Each angular measurement and FHC was also assigned a category of normal, borderline, or abnormal according to the modified values used by Nimityongskul et al[17] and Hosny et al[12] (Table 1). Kappa values for interobserver reliability were then calculated for each category.

An average value was calculated for each measurement on each sonogram. By taking the mean of 3 to 5 values, the accuracy of this figure is approximately double to that of a single measurement. A stepwise linear regression analysis was then performed on these mean values to assess any relationship between ultrasound measurements at 2 or 6 weeks and outcome as determined by AI at 6 months. After the regression was performed, a further regression analysis of the significant independent variables and the requirement for prolonged treatment was performed.

RESULTS

There were 64 babies (128 hips) with 2 scans performed at 2 and 6 weeks of age (248 sonograms). Two babies were missing a 2-week scan and 2 babies a 6-week scan. Each scan was measured by at least 2 examiners, and each examiner remeasured a minimum of 50 scans so that a total of 792 scans were measured and analyzed. Repeatability coefficients are given in Table 2. The value shown is a range within which there is a 95% CI that a second measure will fall from the first. Of the ultrasound angular measurements, the α angle had the smallest range (17 degrees) for interobserver and intraobserver repeatability and the β angle had the worst. The combined angle was intermediate. The FHC had a range of approximately 30%.

Each measurement was categorized as normal, abnormal, or borderline. Kappa values were calculated for intraobserver and interobserver agreement (Table 3). There was good to excellent intraobserver agreement for α, β, and FHC for all categories; and there was good interobserver agreement for hips categorized as normal. The FHC had the best interobserver agreement for hips in the borderline range, and the FHC and β angle had the best interobserver agreement for abnormal hips and overall. The combined angle had the least interobserver and intraobserver agreement for classifying hips in any of the 3 categories.

Details of the mean values and the proportion of hips in each category are given in Table 4. Using the narrower range of 40% to 55% for the borderline zone of FHC as suggested by Nimityongskul et al,[17] we found 68 hips (55%) at 2 weeks and 64 hips (52%) in this category. There were 38 abnormal scans (30%) at 2 weeks, falling to 24 (19%) at 6 weeks. The α, β, and *H* angles were in the abnormal range in only 4% to 6% of hips at 6 weeks.

TABLE 2. Interobserver and Intraobserver Repeatability Coefficients for Ultrasound Measurements and AI

	α	β	Combined	FHC	AI
Interobserver	17.0	27.8	21.1	31.6	8.1
Intraobserver					
1	17.1	31.8	22.8	34.1	7.1
2	17.1	28.4	22.0	34.3	7.2
3	15.4	20.0	16.5	29.3	13.6

The numbers represent the value within which there is 95% confidence that a second observation will fall from the first.

TABLE 1. Normal Values Used for α, β, *H* Angles and *d*/*D* Ratio

	Normal	Borderline	Abnormal
α angle (degrees)	>55	45–55	<45
β angle (degrees)	<55	55–75	>75
H angle (degrees)	<75	75–85	>85
FHC (%)	>55	40–55	<40
	Normal	**Mild Dysplasia**	**Marked Dysplasia**
AI (degrees)	≤25	26–29	≥30

Adapted from Nimityongskul et al[17] and Hosny et al.[12] Acetabular index adapted from Tonnis.[15]

TABLE 3. Interobserver and Intraobserver Agreement for Category of Hip According to Each of the Ultrasound Measurements

		Interobserver			
	Intraobserver	Normal	Borderline	Abnormal	All Categories
α angle	**0.68**	**0.63**	0.48	0.49	0.55
β angle	**0.80**	**0.76**	0.50	**0.93**	**0.77**
H angle	0.53	0.48	0.31	0.44	0.44
FHC	**0.73**	**0.76**	0.59	**0.61**	**0.66**

Expressed as kappa values (0.6–0.8, good agreement; >0.8 excellent agreement).

TABLE 4. Details of Ultrasound and Radiographic Measurements

	No. Hips	Mean (degrees)	SD	Normal No. Hips (%)	Borderline No. Hips (%)	Abnormal No. Hips (%)
2 wk						
α angle	124	51.7	6.7	44 (35)	62 (50)	18 (15)
β angle	124	55.0	12.0	79 (64)	35 (28)	10 (8)
H angle	124	84.0	8.7	67 (54)	35 (28)	22 (18)
FHC	124	41.8	15.5	18 (15)	68 (55)	38 (30)
6 wk						
α angle	124	54.1	6.4	61 (49)	56 (45)	7 (6)
β angle	124	49.1	5.4	101 (81)	20 (16)	3 (3)
H angle	124	88.2	7.0	86 (69)	34 (27)	4 (4)
FHC	124	42.7	11.7	36 (29)	64 (52)	24 (19)
6 mo						
AI	128	26	4.9	62 (48)	42 (33)	24 (19)

Mean values from repeated measurements, numbers and percentages in normal, borderline, and abnormal categories.
α and β angles (Graf), combined angle of Hosny (*H* angle), FHC, and AI.

The mean AI of all hips at 6 months was 26 degrees (SD, 4.9). The AI was 30 degrees or greater in 24 hips (18 babies) despite prolonged splintage in 9 hips (6 babies); 6 of these hips (4 babies) subsequently required closed reduction. A further 42 hips had mild dysplasia (AI, 26–29 degrees). Eight of 12 babies with severe unilateral dysplasia had mild dysplasia of the contralateral hip.

The stepwise linear regression analysis showed that the FHC at 6 weeks was independently predictive of the AI at 6 months (regression coefficient, −0.27; 95% CI, −0.42 to −0.12; $P < 0.001$). None of the other measurements were associated with the AI. There is a significantly different relationship between FHC at 6 weeks and AI for those with prolonged treatment than for those without ($P = 0.034$). However, the main effect of FHC at 6 weeks on AI is not greatly changed ($P = 0.001$ to $P = 0.004$). There is no significant difference in AI between the prolonged treatment group and those without prolonged treatment ($P = 0.6$). Therefore, although prolonged treatment had an effect in combination with FHC, it had no independent effect on the AI.

Of the 24 hips with severe dysplasia, there were 11 with FHC of 40% or less at the 6-week scan, and 10 hips were in the borderline range of 41% to 55%. Only 1 had normal coverage of 62%. The 6-week scans of 2 babies were missing.

DISCUSSION

Although ultrasound is widely used in the diagnosis and management of DDH, there are a number of problems and questions surrounding its use. Scans may be performed by radiographers or radiologists, with or without an orthopaedic surgeon in attendance, and often are reported by radiologists or orthopaedic surgeons from the recorded images. This may affect the reliability of the results. Our measurements were taken from recorded images and none had particularly good reproducibility. The α angle was the best with a 95% CI of 17 degrees compared with 28 degrees for the β angle. Cheng et al[7] found no significant intraexaminer variability for α angle (mean difference, −0.5; SD, 3.2; $P = 0.22$), but there was a significant variation for β angle (mean difference, 2.7; SD, 7.5; $P = 0.0037$). Roovers et al[10] found mean interobserver within-subject SDs of 3.2 degrees for α angle and 6.0 degrees for β angle. However, neither of these articles quoted 95% CI. Dias et al[8] found only fair reproducibility with limits of agreement of 11.4 degrees for intraobserver and 12.6 degrees for interobserver for the α angle compared with 14.9 and 19 degrees for β angle. Hosny et al[12] found limits of agreement of 6.24 to 9.64 degrees for α angle and 11.8 to 13.3 degrees for β angle, but found the combined (*H*) angle to be the most reproducible, with agreement limits of 2.2 to 4 degrees. In contrast, we found this angle difficult to measure accurately; and our interobserver limits of agreement were approximately 21 degrees. Femoral head coverage as determined by the bony rim percentage or *d*/*D* ratio has been found to be reproducible. Measuring bony rim percentage, Terjesen et al[18] found a mean difference of 3.9% (SD, 3.2; range, 0%–12%) for intraobserver reliability and 3.4% (SD, 2.7; range, 0%–10%) for interobserver reliability. Hosny et al[12] found limits of agreement of 8.9% to 12.4% for bony coverage. Jomha et al[19] found that bony rim percentage measurements were quite repeatable but had a significant difference between examiners. A very high proportion of measurements (93%) fell into the wide borderline zone of Morin et al[6] (*d*/*D* ratio between 33% and 58%), which limits its usefulness in practice. Riad et al[9] found that the FHC in normal hips varies with age and at 6 weeks averaged 66%, with 55% the lower limit of normal (SD, −2). They reported narrow 95% CI of agreement of 7% to 8%, which they attributed to skilled pediatric sonographers who took the measurements at the time of the scan.

The FHC in our series had a wider range of limits of agreement than we expected at around 32% for 95% CI. This may be explained in part by the inaccuracy of taking linear measurements from a small printed image. It also may reflect the wider range of values due to the high incidence of abnormal

hips in our group when compared with other series that had a majority of normal hips. We found better agreement when hips were categorized into normal, abnormal, or borderline, with the FHC and β angle showing the best overall agreement. The *H* angle had the worst interobserver and intraobserver agreement for all categories.

The other significant problem of ultrasound is that it detects many abnormalities in the first few weeks of life that resolve spontaneously.[20–23] A scan at 4, 6, or 9 weeks is more specific than an earlier scan;[20,22,24] but this limits its usefulness in screening. Sucato et al[23] looked at the natural history of ultrasound abnormalities in clinically stable hips and found that no ultrasound measure at less than 1 month of age was predictive of dysplasia. Castelein et al[21] found only 4 of 144 hips with isolated ultrasound abnormalities at birth that developed acetabular dysplasia.

In a general ultrasound screening program, 38% of grade 5 (dislocated) hips at birth, 8.5% of grade 4 hips (mean BRP, 28.6% ± 8.4%), and 2.75% of grade 3 hips (mean BRP, 51.6% ± 7%) required treatment after they failed to resolve by 6 weeks of age.[20,22]

Engesaeter et al[11] reported that in a group of 100 babies referred to the DDH clinic with risk factors or instability, only dynamic stability correlated with radiographic outcome. The unstable hips in their group did not have a significantly lower *d*/*D* ratio than the stable hips.

Hangen et al[2] found that there was no clearly significant relationship between stability and geometric measurements in treated unstable hips. They noted an improvement in α angle in successfully treated hips and found that ultrasound was particularly helpful in identifying treatment failure early.

In our group, all hips were clinically unstable (dislocated or dislocatable) when examined by an orthopaedic surgeon within a day or two of birth and therefore were treated in a Pavlik harness. It is accepted that up to 60% of hips unstable at birth may spontaneously stabilize.[25] However, in this group of babies, we would still expect to see a high proportion of abnormal scans. This is reflected in the low mean values for α angle and FHC at 2 and 6 weeks. By taking 55% as the lower limit of normal for FHC at 6 weeks and less than 40% as abnormal, we found 24 abnormal (19%) and 64 borderline (52%) hips at 6 weeks. Eleven of these hips subsequently developed severe radiographic dysplasia at 6 months (AI > 30 degrees). The α and β angles and the combined angle of Hosny were only abnormal in 4% to 6% of the hips in our study at 6 weeks, suggesting that these angular measurements are not sensitive enough to be useful in practice. In contrast, Irha et al[26] have suggested that linear parameters are less sensitive than angular measurements for dysplastic hips but were highly specific for normal hip development.

Unlike other authors,[2,11] we found that the FHC at 6 weeks was predictive of outcome at 6 months as determined by the AI. This is not a natural history study, as all hips were treated until the 6-week scan when we used persisting instability or low FHC as our criterion for further splintage. If we had not continued treatment in those hips with a low FHC at 6 weeks, then the association may have been stronger. The AI at 6 months was used as the end point of this study. We do not necessarily regard this as predictive of the final outcome of an individual hip. However, all hips in this study that required subsequent surgical treatment had an AI of greater than 30 degrees at 6 months.

This study has focused on static measurements. However, it is very important that a dynamic assessment of the hip is performed at the time of the ultrasound, as a scan should not be considered normal based on static morphology alone, especially in the first month of life. We believe this is best done by an orthopaedic surgeon. We rely on clinical examination for diagnosis at birth and use ultrasound mainly to monitor response to treatment.

We believe that the FHC is the most useful static measurement in assessing a baby with DDH. This study shows that it is reproducible in determining the category of a hip and, at 6 weeks, is predictive of the AI at 6 months in hips treated from birth for instability.

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Late presenting dislocation of sonographically stable hips

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We report on seven developmental hip dislocations in five babies (age 6–22 months) in whom ultrasound had demonstrated reduced and stable hips. Four hips in three babies had been diagnosed as having clinical instability (Barlow positive) at birth, which had stabilized by the time of the scan (16–45 days). Femoral head coverage ranged from 36 to 56%. One hip had minimal sonographic laxity on stress examination. Hips that are reduced and stable sonographically at 2–6 weeks of age can subsequently dislocate. Any child with instability at birth should be reviewed with a pelvic radiograph at 4–6 months, even if an ultrasound scan appears to be normal. *J Pediatr Orthop B* 15:257–261 © 2006 Lippincott Williams & Wilkins.

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Study conducted at the Dunedin Public Hospital, Dunedin, New Zealand.

Introduction

Developmental dysplasia of the hip (DDH) is a spectrum of disease ranging from irreducible dislocation at birth to mild acetabular dysplasia. The change in terminology from congenital dislocation of the hip reflects this and also implies that the abnormality may not be present at birth [1]. The majority of cases are detectable at birth and, of these, approximately 60% subsequently stabilize [2]. Rarely, however, clinically stable hips may subsequently dislocate [3,4]. Ultrasound has demonstrated abnormalities not detectable on clinical examination, but most of these spontaneously resolve [5,6]. Therefore, there has been a trend towards treating only those hips that fail to stabilize or those that have persisting ultrasound abnormalities at 6–8 weeks [7–9].

The purpose of this report is to describe five babies in whom ultrasound demonstrated reduced and stable hips and relatively minor morphological abnormalities that subsequently developed established dislocations.

Methods

Screening programme

We have used ultrasound in the diagnosis and management of neonatal hip instability for 15 years [10]. Three orthopaedic surgeons examine all babies in hospital and scan babies with hip instability or risk factors. We treat dislocated (Ortolani positive) hips from birth with a Pavlik harness, but delay treatment when there is uncertainty or more minor instability. Scans are performed at 2 weeks and at 6 weeks if there are persisting clinical or sonographic abnormalities. A sonographer performs the scan with an orthopaedic surgeon present. A static coronal scan is performed with the transducer placed laterally. An anteroposterior transverse scan is then obtained and a stress view taken as the surgeon performs Barlow's manoeuvre. We have not formally measured angular measurements of the acetabulum but assess the femoral head coverage (FHC), acetabular morphology and stability. Pelvic radiographs are performed after 4–6 months.

Case 1

Case 1 is of the second-born girl of a normal pregnancy with no risk factors. She was born in another hospital and examined at birth by a consultant paediatrician who diagnosed bilateral hip instability. When she was seen in our ultrasound clinic at 5 weeks of age both hips were reduced and stable clinically and on ultrasound. The FHC was low borderline at 36 and 41% according to the criteria of Morin *et al.* [11].

As a result of geographical remoteness, the patient did not return for review until 6 months of age at which time she had bilateral hip dislocations. She required closed reduction, adductor tenotomy and hip spica for 3 months and subsequent abduction bracing. Despite this, she has persisting acetabular dysplasia at 7 years with centre-edge angles of 12° right and 10° left hip.

Case 2

Case 2 is of a girl, breech presentation with no family history of DDH, born at 36 weeks gestation. The hips were examined by an orthopaedic surgeon and found to be stable at birth. An ultrasound was performed in view of the breech presentation at 31 days and the hips were reduced and stable. By Graf's criteria [12], the right hip was type II and the left hip type I. The FHC was 36% (right) and 37.5% (left). No treatment was instituted. A second scan was performed at 45 days, which showed

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both hips were reduced and stable with slightly improved head coverage at 40%.

The patient failed to present for follow-up radiology at 4–6 months. She re-presented at 22 months with a dislocated right hip. She underwent a closed reduction and adductor tenotomy but later required a right Salter pelvic osteotomy at 5 years 6 months.

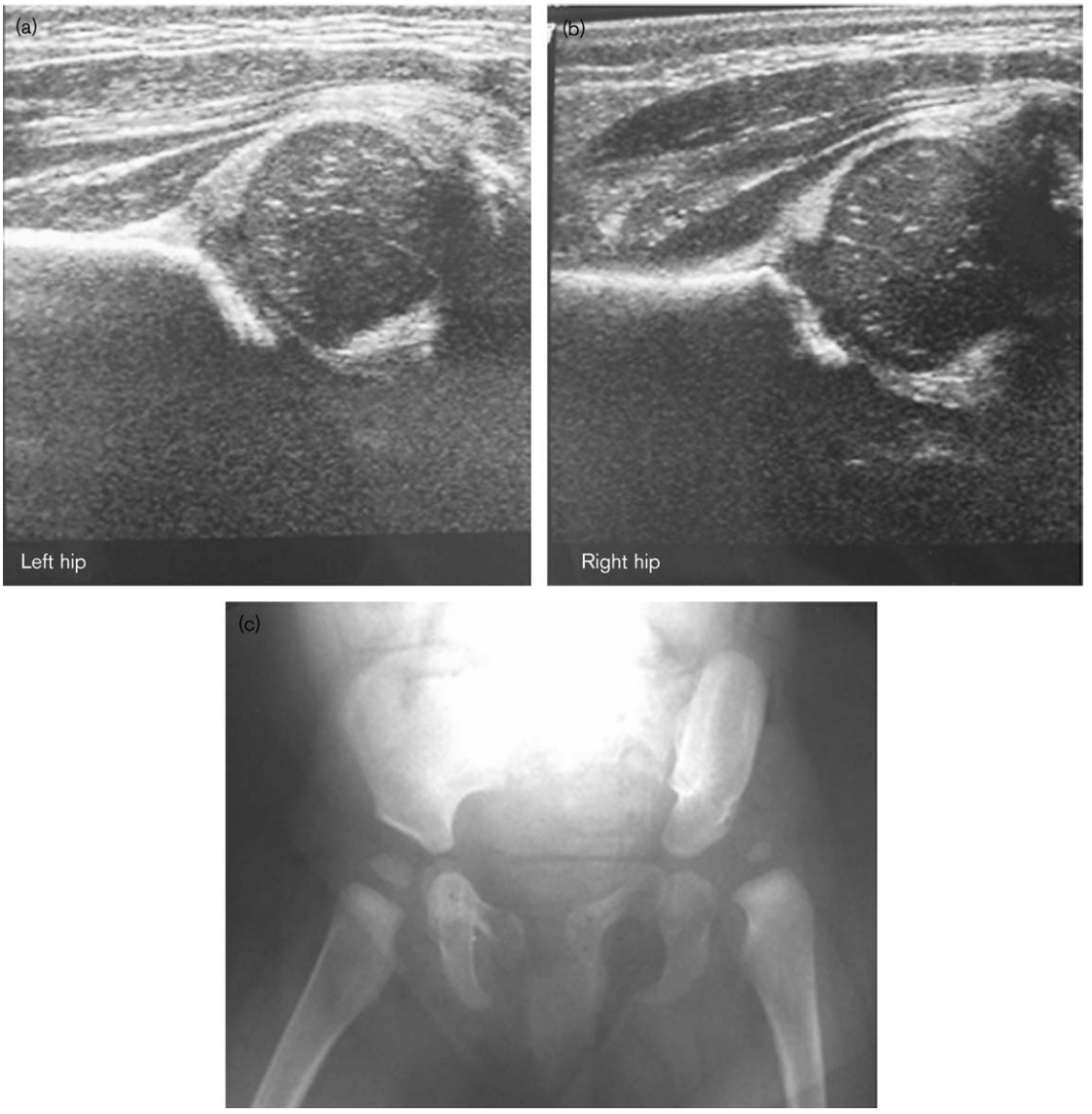
Case 3

Case 3 is of a first-born girl, with no family history of DDH, a cephalic presentation and a forceps delivery at 39 weeks. When examined at birth by an orthopaedic surgeon there was laxity of the left hip (Barlow positive, Ortolani negative). At 16 days the hip was clinically stable. A little laxity on ultrasound but a well formed acetabulum (Graf I) and an FHC of 50% were noted. (Fig. 1a and b) Therefore, no treatment was instituted. Follow-up radiographs were not obtained until 7 months of age and showed a dislocated left hip (Fig. 1c). The patient underwent closed reduction, adductor tenotomy and hip spica followed by abduction bracing.

Case 4

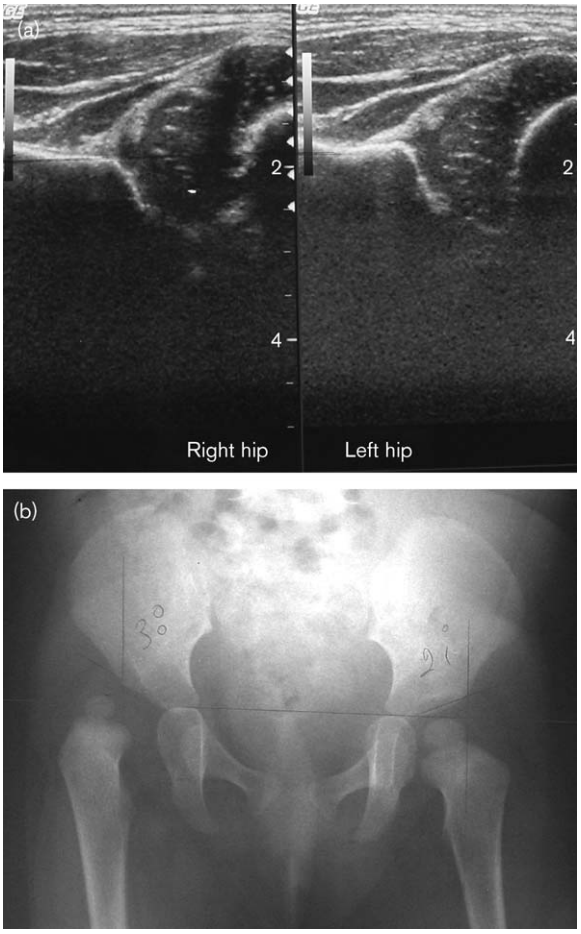
Case 4 is of a girl, a cephalic presentation with no risk factors, who, on a neonatal hip examination, had a Barlow-positive right hip. This was not treated initially. At 20 days of age, she had no clinical instability and an

Fig. 1



Case 3. Ultrasound (coronal) left hip (a), right hip (b) and radiograph pelvis at the age of 7 months showing dislocated left hip (c)

Fig. 2



Case 4. Coronal ultrasounds of hips (a) and radiograph pelvis at the age of 9 months showing dislocated right hip (b).

ultrasound showed a well formed acetabulum (Graf I) with no instability (Fig. 2a). The FHC was 41% for the right hip. No formal follow-up was arranged and she was referred back at 9 months with a dislocated right hip (Fig. 2b). She was treated with closed reduction and hip spica.

Case 5

Case 5 is of a girl, second child born by caesarian section at full term. Both hips were stable at birth according to an orthopaedic surgeon. An ultrasound was performed at 5 weeks in view of a maternal history of DDH. No instability was observed. The hips were Graf type II with an FHC of 43% on the right and 45% on the left. No treatment was instituted but at review at 7 months of age she was found to have bilateral dislocations. She underwent a closed reduction and adductor tenotomy.

Discussion

Screening programmes by experienced examiners have reduced late presenting DDH to very low levels (0.2 per 1000) [13]. It has been recognized that not all cases of DDH can be identified at birth by clinical examination [1,3]. Ultrasound can detect abnormalities not apparent on clinical examination but 90% may resolve by 9 weeks [5,6]. Marks *et al.* [6] noted that their rate of detection of unstable hips by ultrasound alone (0.57 per 1000) was very similar to their historical rate of late presenting DDH (0.68 per 1000). Subsequently, Bache *et al.* [7] have reported no cases of late presenting DDH, as a global ultrasound programme was instituted with static views obtained by a sonographer at birth. Therefore, it appears that there is a small group of babies who may have persisting ultrasound abnormalities that would not otherwise be detectable by clinical screening [5,6].

In continental Europe, orthopaedic surgeons may perform the ultrasound examination but elsewhere in the world it is more commonly performed by radiologists or sonographers [14]. An ultrasound scan should include a scan in the coronal plane with the hip at rest, and a dynamic assessment in the transverse plane with the hip under stress [14]. Acetabular morphology is assessed from the coronal scan and most commonly classified using the system of Graf [12]. Many hips are immature with an α angle between 50 and 60° and should be observed, while $< 50°$ is abnormal [15]. No angular measurements before 4–6 weeks of age are predictive of outcome [5]. A recent review recommended a scan at 4–6 weeks of age and stated that angular measurements of acetabular landmarks are optional [14].

Morin *et al.* [11] described the *d*/*D* ratio as normal if $> 58\%$, borderline if 33–58% and abnormal if $< 33\%$. The wide borderline zone, however, limits its usefulness in screening [16]. Nimityongskul *et al.* [15] modified the classification and defined a *d*/*D* ratio of $> 55\%$ as normal, 40–55% as borderline and $< 40\%$ as abnormal, while Terjesen *et al.* [17] defined hips with $< 50\%$ FHC coverage at birth as potentially abnormal. We have not routinely measured angles but look at the general morphology, stability and FHC. We now regard hips with less than 40% coverage as abnormal (Table 1).

At the time of the ultrasound scan, nine of the hips in our group were stable clinically and on ultrasound, and one hip with minimal laxity on stress views had a normal acetabular morphology. If we categorized the babies according to Graf's morphological system, then of the seven dislocated hips, two were type I and five were type II. The FHC was in the borderline zone of Morin *et al.* [11] in all 10 hips, including those seven that subsequently dislocated. Using the modified criteria of Nimityongskul *et al.* [15], there was one normal hip, eight borderline hips of which six subsequently dislocated and one abnormal hip. This hip (patient 1, right

Table 1 Details of patients, ultrasound measurements (α angle, β angle and *d/D* ratio) and outcome

Patient	Neonatal examination	Age at scan (days)	Stability at ultrasound scan	Right			Left			Outcome
				α	β	*d/D*	α	β	*d/D*	
1	Both hips unstable	35	Stable	48°	52°	36%	50°	50°	41%	Bilateral dislocations 6 months
2	Stable	31	Stable	54°	50°	36%	60°	55°	37.5%	
		45	Stable	51°	56°	40%	56°	57°	40%	Dislocated right hip at 22 months, mild dysplasia left hip
3	Left hip dislocatable	16	Clinically stable, mild laxity on stress ultrasound left hip	60°	58°	50%	60°	58°	50%	Dislocated left hip at 7 months
4	Right hip dislocatable	20	Stable	60°	54°	41%	60°	50°	56%	Dislocated right hip at 9 months
5	Both hips stable	36	Stable	55°	55°	43%	55°	50°	45%	Bilateral dislocations at 7 months

hip), in retrospect, should have been treated despite being reduced and stable sonographically at 6 weeks.

A widespread trend is to delay treatment until there are persisting ultrasound abnormalities or clinical instability. Splintage rates have been reduced from 16 per 1000 [13] with a clinical screening programme to 3–6 per 1000 [7,9,18–20] when an ultrasound is used. We have previously reported a splintage rate of 5.4 per 1000, of which 93% were treated from birth [10]. More recently, we have tended to delay splintage of unstable hips until the baby is seen at the ultrasound clinic. The five babies who comprise this report were all identified by the screening programme initially and were born since this change in practice. A natural reluctance to start splintage at the time of scan is noted if the hip is stable and there are only borderline sonographic abnormalities. We find it concerning that two of these babies (cases 3 and 4) with laxity at birth had what we usually regard as acceptable stability and morphology at the time of their scan, and were therefore not splinted, whereas previously they might have been splinted from birth for 6–8 weeks.

Patients 2 and 5 had clinically normal hips from birth, which were also stable on ultrasound. These patients belong to the small group described by Marks *et al.* [6], in which abnormal hips can only be detected by ultrasound. The FHC in these cases, however, was in the borderline zone and not clearly abnormal.

The change in terminology from congenital dislocation to developmental dysplasia as advocated by Klisic [1] is important medicolegally. It recognizes the spectrum of disease from neonatal dislocation to acetabular dysplasia. It remains controversial whether dislocations are 'missed' on neonatal screening or whether the hip can dislocate late. The phenomenon of a late developmental dislocation is well recognized by paediatric orthopaedic surgeons but there has been little radiographic evidence to support this view, to our knowledge, in the English language literature. Ilfeld *et al.* [4] reported on 15 cases of late dislocation after repeated normal clinical examinations by experienced surgeons. In only three of the cases, however, had normal radiographs been documented, of which two were taken in the first week of life and one at 31 months during treatment of dislocation of the contralateral hip. Babies with persisting ultrasound abnormalities have been treated by some authors, with a reduction in the rates of late dislocation and acetabular dysplasia [7], but it is not clear which babies should be treated and which will develop problems.

We believe that these cases add support to the concept of late developmental dislocations. They demonstrate that hips that are reduced and stable clinically and sonographically at 2–6 weeks, with either a normal scan or borderline ultrasound abnormalities, can develop an established dislocation. It is important that an ultrasound must be interpreted in combination with the clinical findings and should include a stress view, preferably performed with an orthopaedic surgeon present. All babies should have careful follow-up with a pelvic radiograph at 4–6 months if there has been instability at birth or persisting ultrasound abnormality.

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Chapter 4

Alternatives to surgery: Improving non-operative management.

a) The Joint Clinic

A general principle of elective surgery is that it should be used after failure of non-operative treatment. In patients with osteoarthritis of hip and knee this should include lifestyle modifications, physiotherapy and exercise, simple analgesia and non-steroidal anti-inflammatory drugs. These can usually be co-ordinated in the primary care setting but there has been a move toward a chronic disease management approach using multi-disciplinary clinics.

We developed the Joint Clinic, as part of the Orthopaedic Patient Pathway Programme, based on similar clinics in Australia. Its goal was to improve access to the orthopaedic service for patients with hip and knee OA. Many patients referred by their GP for consideration of THR and TKR were being declined an orthopaedic appointment due to capacity constraints. Best practice protocols were developed to improve non-operative care of these patients with the ability to refer those in most need on for surgical management. This series of papers covers its development and implementation, the results of the first 2 years of operation, the factors associated with response to treatment and the 5 year outcomes. The final paper in the Joint Clinic series, '*The functional outcomes of patients with knee osteoarthritis managed non-operatively at the Joint Clinic at 5 year follow up: Does surgical avoidance mean success?'* compares patient reported outcomes in attempt to determine whether avoidance of surgery constitutes successful non-operative management. The findings showed that patients who had undergone surgery had improved functional outcomes compared with those that had continued non-operative treatment.

b) Comparing operative and non-operative treatment.

There are relatively few randomized controlled trials of orthopaedic surgical procedures which leads to criticism from advocates of evidence-based medicine. Surgery is usually reserved for failure of non-operative treatment. If there is a subsequent improvement it is taken as evidence of surgical success. In the acute setting it is not possible to trial non-operative treatment for extended periods. A decision usually needs to be made soon after presentation. If the results of non-operative treatment are equivalent to surgery there is the potential to reduce the operative burden on the hospital and reduce the risk of potential harm to the patient.

Management of acute Achilles tendon rupture has always been a controversial topic amongst orthopaedic surgeons. Many surgeons believe that there is a lower re-rupture rate and improved functional outcomes with surgery. Improvements in management including functional bracing led to us developing an identical rehabilitation protocol in patients treated both surgically and non-operatively. We report on the epidemiology of this injury and the results with respect to re-rupture and surgical complications of this protocol in '*Acute Achilles Tendon Rupture: Epidemiology and outcomes of 363 patients with operative or non-operative treatment using an identical functional bracing protocol.'* We found a higher rate of this injury in woman than previously reported elsewhere. This allowed some

comparison of gender differences. The paper does still show an advantage to surgery in terms of a reduced re-rupture rate which is consistent with meta-analyses in the literature. The surgical complication rate including re-ruptures was very low compared with major international centres. Non-operative management including functional bracing resulted in low re-rupture rates in patients over 40 years especially in females. The paper has been highly cited indicating its global relevance (52 citations).

The follow up to this study '*Functional outcome of acute Achilles tendon rupture with and without operative treatment using Identical functional bracing protocols* ' compares the functional outcomes at longer term follow up. It showed no difference in patient reported outcomes using the Achilles tendon rupture score (ATRS) and gratifyingly high scores compared to other series.

BMC Musculoskeletal Disorders

RESEARCH ARTICLE Open Access

Implementation of a 'Joint Clinic' to resolve unmet need for orthopaedic services in patients with hip and knee osteoarthritis: a program evaluation

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Abstract

Background: Osteoarthritis is the most common form of arthritis, principally affecting the older population. Highly prevalent, disabling diseases such as osteoarthritis strain the capacity of health systems, and can result in unmet need for services. The Joint Clinic was initiated to provide secondary care consultations and access to outpatient services for people with advanced hip or knee osteoarthritis, who were referred by their general practitioner for orthopaedic consultation but not offered an orthopaedic specialist appointment.

Methods: This longitudinal programme evaluation comprised four components: a proof-of-concept evaluation; an implementation evaluation; a process evaluation; and an outcomes evaluation. Interviews and surveys of general practitioners, staff, and patients were conducted pre- and post-implementation. Interviews were transcribed, and thematic analysis was completed. In addition, Joint Clinic patient visits and outcomes were reviewed.

Results: One hundred and eleven primary care physicians (GPs) and 66 patients were surveyed, and 28 semi-structured interviews of hospital staff and GPs were conducted. Proof of concept was satisfied. Interim and final implementation evaluations indicated adherence to the concept model, high levels of acceptance of and confidence in the programme and its staff, and timely completion within budget. Process evaluation revealed positive impacts of the programme and positive stakeholder perceptions, with some weaknesses in communication to the outer context of primary care. The Joint Clinic saw a total of 637 patient visits during 2 years of operation. Unmet need was reduced by 90%. Patient and referring physician satisfaction was high. Hospital management confirmed that the programme will continue.

Conclusions: This evaluation indicates that the Joint Clinic concept model is fit for purpose, functioned well within the organisation, and achieved its primary objective of reducing unmet need of secondary care consultation for those suffering advanced hip or knee osteoarthritis.

Keywords: Orthopedics, Osteoarthritis Knee, Osteoarthritis Hip, Osteoarthritis/Therapy, Referral and consultation, Secondary care, Primary health care, Program evaluation

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Background

Osteoarthritis (OA) is the most common form of arthritis, principally affecting the older population. The Global Burden of Diseases, Injuries, and Risk Factors Study 2015 found that the prevalence of OA increased 32% between 2005 and 2015 [1]. The high prevalence and increasing disability burden of OA mean it is a high priority condition, and has been formally recognised as such by the World Health Organisation (WHO) [2].

Many health systems worldwide will need to adapt to a higher proportion of older people as population demographics change. In New Zealand, those over the age of 65 years will make up over one quarter of the population by the late 2030's [3]. Osteoarthritis of the hip and knee is the most common condition for which joint replacements are indicated, and as the population ages, demand for joint replacement surgery is predicted to rise significantly [3]. This scenario will place significant stress on the health resources in New Zealand. The Southern District Health Board (SDHB), the public health services provider for Dunedin, New Zealand, has seen a substantial rise in demand for joint replacement surgery, and a shortfall of orthopaedic specialist resources to meet the demand of general medical practitioner (GP) referrals for patients with osteoarthritis [4, 5]. This has resulted in a growing unmet need for secondary care consultations and OA management. A report by the SDHB general practitioner liaison [6] and subsequent audit research [4] found that up to 44% of patients with OA of the hip or knee referred for orthopaedic specialist consultation were unable to be offered an appointment, and were instead referred straight back to the referring GP without review or advice regarding ongoing management.

The Joint Clinic, a clinical service of the Orthopaedic Outpatient Department, Dunedin Hospital, was proposed and introduced to address the unmet need for secondary care consultation for people with late-stage hip and knee OA. Contemporary clinical practice guidelines for the management of OA recommend non-operative interventions – including exercise therapy and education – as core, first line management for all patients with hip or knee OA [7–9]. The Joint Clinic proposal was based on locally conducted research into the effectiveness of non-operative interventions [10–13]. The Joint Clinic was designed to contribute to the New Zealand Ministry of Health objective to provide *better, sooner, more convenient care* by improving the management of hip or knee OA at the interface between primary and secondary care [13, 14]. There is evidence to show that multidisciplinary collaboration and communication are essential to promote continuous, coordinated, patient-centred care with regard to OA [15].

The goal of this study was to conduct a comprehensive, longitudinal programme evaluation of the implementation of the Joint Clinic initiative. This programme evaluation was planned a priori and completed to assess whether the initiation and operation of the Joint Clinic achieved its four main objectives. These four objectives were to establish whether or not: 1) a physiotherapist-led clinic in a secondary care setting would be feasible as a method of meeting an unmet need for secondary care consultations and management in patients with hip or knee OA; 2) this new programme could be successfully implemented as proposed; 3) the new programme would operate as planned and be well accepted by stakeholders; and 4) the Joint Clinic was perceived to bridge the gap in care of those with OA of the hip and knee in a secondary setting in a cost-effective way, increase efficiency in its secondary care setting, and provide support for GPs in primary care.

Methods

The 'Joint Clinic' programme

The Joint Clinic was developed as a clinical service of the Orthopaedic Outpatient Department at Dunedin Hospital. The patient referral pathway for OA patients referred from primary care to the Orthopaedic Department is illustrated in Fig. 1. To be eligible for inclusion, patients must have undergone clinical assessment by their GP and referred for orthopaedic consultation in secondary care (Dunedin Hospital) including current plain radiographs.

It was proposed that advanced competency physiotherapists would examine patients with hip or knee OA referred to the orthopaedic department and provide initial conservative management, education, referral and reassurance. A key component was referral to outpatient physiotherapy for a programme of exercise physiotherapy, when indicated, delivered either individually or in groups, in 6 visits of 40 min duration (see Additional file 1). Referrals could be made to an orthopaedic consultant, orthotics, dietetics, or community physical activity providers. All eligible patients managed in the Joint Clinic services would be followed up in clinic every 6 months until discharged. Discharge would occur when the programme course was completed, the patient stable, or when referral elsewhere was indicated. It was planned that the Joint Clinic would accomplish this with the support of an experienced orthopaedic nurse, consultant orthopaedic surgeons, and the Outpatient Physiotherapy Department.

The goals of the Joint Clinic programme were to increase efficiency in secondary care by decreasing time spent by Orthopaedic Consultants on patients not requiring surgery; to provide a much needed support for GPs in primary care by providing review and advice regarding ongoing management; to meet the unmet need described above; to improve patient outcomes; and demonstrate potential to make savings in both direct and indirect economic costs.

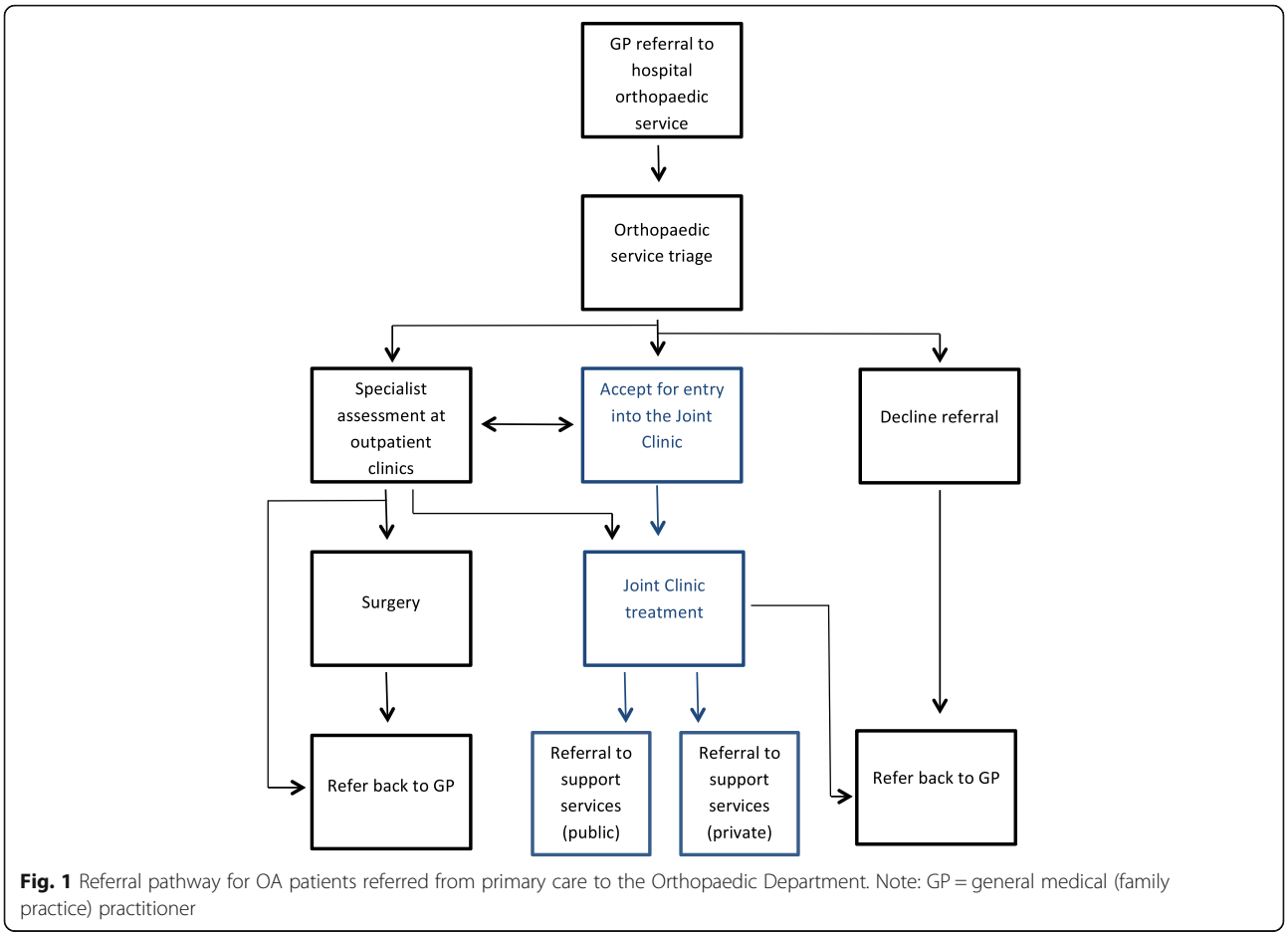

Fig. 1 Referral pathway for OA patients referred from primary care to the Orthopaedic Department. Note: GP = general medical (family practice) practitioner

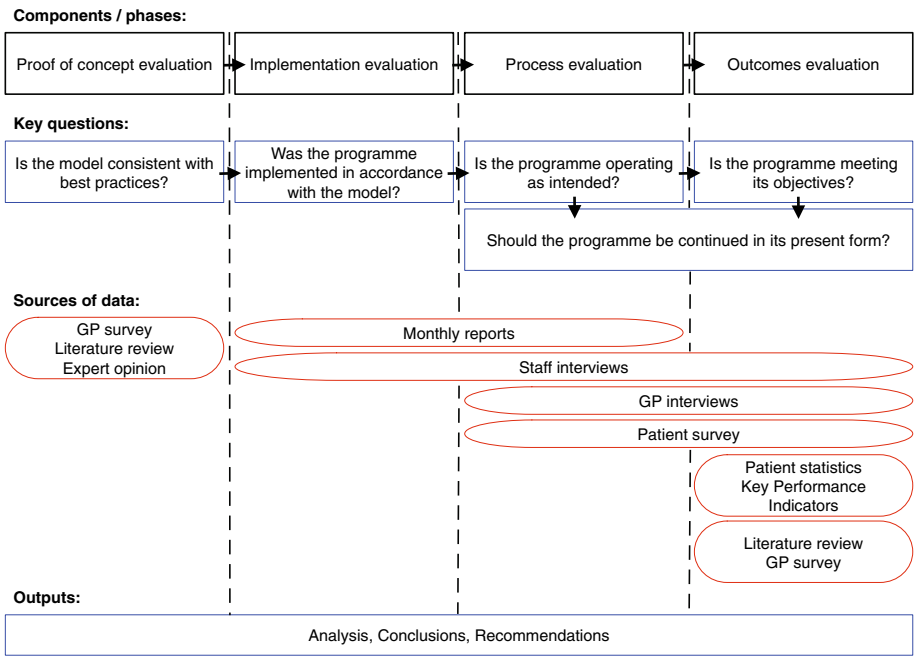

Fig. 2 Components of the programme evaluation. Note: GP = general medical (family practice) practitioner

Programme evaluation study design

This study was an utilisation-focussed, end-to-end programme evaluation of the Joint Clinic. We structured and conducted the evaluation using the framework described by Hollander et al. [16] An overview of the evaluation structure and data collection methods are summarised in Fig. 2. The programme logic model is reported in Additional file 2. The initial phase was a *proof-of-concept evaluation.* In this phase the rationale for the programme was evaluated, the need for the service in the local community was assessed, and the key characteristics of the model were weighed against best practices in the field. An *implementation evaluation* was conducted, in an interim and a final phase. This assessed the extent to which the programme was executed in accordance with the proposed model. In concert, a *process evaluation* was done to assess whether the programme operated smoothly and efficiently, was adequately resourced and staffed, and was functioning as intended. Finally, an *outcomes evaluation* investigated whether or not the programme was achieving intended outcomes and objectives.

The primary outcome that the programme intended to address was unmet need for orthopaedic consultations for patients referred with OA, measured by number (proportion) of referrals sent back to the GP without consultation. Secondary outcomes included GP satisfaction with the service, acceptability of the programme by providers and patients, and service-level efficiency outcomes. Key outcomes assessed in each of the phases of the programme evaluation are summarised in the programme logic model (Additional file 2).

Literature review and expert opinion

The literature review and appraisal of expert opinion were conducted to indicate whether or not a physiotherapist-led clinic in a secondary care setting would likely be feasible and effective as a method of meeting an unmet need. The model was assessed against best practices, as identified by a review of the literature [15, 17–20], and by the leaders and staff of comparable OA clinics in Australia. Principals and staff from these clinics were consulted, site visits were conducted, and key characteristics of those services considered in the context of best practice recommendations [15, 17, 19, 20]. The programme was based on principles of chronic care [21–23]. Interventions included within the model, in particular the key physiotherapy component were investigated for support by clinical practice guidelines of effectiveness research [7–10], as well as a systematic review of cost-effectiveness [24].

Surveys of GPs, staff, and patients

Both pre- and post-implementation surveys and interviews were conducted, to assess objectives 2 and 3 relating to implementation and process. Survey design and delivery was based on best-practice evidence from the literature [25]. The surveys [see the appendices in Additional file 3] were intended to gauge Dunedin GPs' satisfaction with the Orthopaedic Outpatient Department service, as well as their opinion regarding the need for the proposed new service. The pre-implementation survey consisted of three questions regarding access to an orthopaedic first specialist appointment (FSA). The post-implementation version consisted of eight questions; the first three questions were the same as those in the first survey, and the next five questions were about perceptions of the Joint Clinic operations. Participants were also invited to add free-text comments at the end of the survey.

All Dunedin GPs were mailed the survey, a reply-paid envelope and a pen [25]. After 4 weeks, non-responders with a known email address were sent an email with a link to the survey online. Non-responders without a known email address were posted a reminder letter, a second copy of the survey and a reply-paid envelope.

Each patient who had been seen for at least one follow-up appointment at the Joint Clinic by the end of year 1, was mailed a user perceptions survey [see the appendices in Additional file 3]. Eligible patients were contacted in the same manner as the GPs. Two weeks later non-responders were sent a reminder letter and another copy of the survey. The survey aimed to assess patient satisfaction at the Joint Clinic. The survey included questions about their satisfaction with wait time, the knowledge and expertise of staff, the treatment offered their overall experience, and whether or not they would recommend the Joint Clinic to others.

Interviews of GPs and staff

One-on-one interviews were conducted at the interim and post-implementation phases. The sampling frame included staff members from the Joint Clinic and the wider orthopaedic service, administration and management personnel, and GPs. In the interim evaluation, key stakeholders of the Joint Clinic were identified and invited to interview, and a chain sampling technique was used to recruit further interviewees. Two interviewers conducted the interim evaluation interviews. Chain sampling is a respondent-driven process, and involves identifying potential participants from key informants, and thus produces a 'snowball' effect [26]. In the post-implementation evaluation, six Southern District Health Board (SDHB) staff and seven General Practitioners (GPs) were invited to take part in a one-on-one in-depth interview. One interviewer (HH), familiar with the institution and environment and experienced in qualitative

research, conducted the interviews. SDHB staff invited to take part were those identified as being closely involved with the Joint Clinic. GPs were selected, from those GPs referring patients that had had a follow-up appointment at the Joint Clinic, using a semi-random process to ensure that each GP interviewed was from a different practice.

The semi-structured interview questions aimed to assess the appropriateness, efficiency and effectiveness of the model's implementation. Questions focussed on appropriate care provision, continuity of care, and competence of personnel [see the appendices in Additional file 3]. Interviews included open-ended questions to elicit large amounts of information from a relatively small number of key informants, to maximize data saturation. Thus, interviewees could produce specific answers as well as varied broad perspectives of individual experiences, opinions and motivations [27].

Monthly reports and patient-level data

To complement the surveys and interviews, monthly reporting on service-level and patient-level statistics were used to inform the outcomes evaluation. Monthly reports generated by the SDHB implementation project team provided statistics regarding department referrals, patient visits and pathways of care. A financial report was produced by the SDHB Business Analyst, and compared against the project budget.

Data analysis

Survey data were analysed using Excel 2011 (Microsoft), and descriptive statistics were used to describe survey results. Themes were analysed from free-text comment data, and the main ideas were summarised.

All interviews were digitally recorded and transcribed by an independent transcription company. Transcriptions were checked against the interview recordings by the interviewer and corrected if necessary. Thematic analysis was carried out, which involved stages of familiarisation, identification of a thematic framework, indexing, charting and mapping and interpretation, based on the Framework Method [28]. NVivo software, version 10 (QSR International Pty Ltd), was used to organise the data [29].

Descriptive statistics were tabulated for service-level outcomes, the net marginal unit cost for all Joint Clinic services and physiotherapy treatments provided was calculated, and costs of programme implementation assessed against the budget allocated. Patient-level outcomes have been reported separately [30, 31].

Results

Surveys of GPs, staff, and patients

Pre-implementation surveys were sent to 111 GPs. Eighty-one respondents completed the survey, for a 73% response rate. The survey found that approximately 90% of GPs were 'unsatisfied' or 'very unsatisfied' with the access to FSA for their patients with advanced hip or knee OA. Once referred patients were seen, however, approximately 65% of GPs were 'satisfied' or 'very satisfied' with overall patient management provided, although approximately 30–35% expressed dissatisfaction with the overall management of their patients. Specific comments indicated that GPs thought *"getting patients into the system is difficult"* and *"too many referrals are returned unseen"*, and that *"Re-referral wastes time (GP and Specialist)"* [see the appendices in Additional file 3].

Post-implementation surveys were sent to 111 GPs. Fifty-eight surveys were completed, for a response rate of 52%. Most GP respondents (78%) had patients seen at the Joint Clinic. The majority of GPs (91%) remained 'very unsatisfied' or 'unsatisfied' with patient access to a FSA. Sixty percent of GPs reported being 'satisfied' or 'very satisfied' with overall patient access to the Joint Clinic; however, 40% reported being 'unsatisfied'. Most GPs (91%) were 'satisfied' or 'very satisfied' with the quality and timeliness of feedback from the Joint Clinic appointment, and 76% were 'satisfied' or 'very satisfied' with the overall patient management regarding the Joint Clinic [see the appendices in Additional file 3 for figures and additional data].

Specific comments about the Joint Clinic indicated that GPs were *"… very pleased to have the Joint Clinic in the current environment where specialist appointments are so difficult to get"* and *"I think the joint clinic overall does a good job. I think patients also appreciate this service"*. However, some thought the Clinic added to the waiting problem, saying *"In my experience the Joint Clinic whilst no doubt well-intentioned functions as a further delay for patients whose need for joint replacement is already pressing by the time I have made a referral to orthopaedics"*, and suggested that *"…The joint clinic would be good for those at an earlier stage of the disease process - not those really for an operation but declined because of insufficient funding"*.

The patient survey indicated the majority of patients were 'satisfied' or 'very satisfied' with the knowledge and expertise of Joint Clinic staff (98%), the treatment plan given by Joint Clinic staff (89%), their treatment at Physiotherapy Outpatients (92%) and other treatments provided (82%). Most patients were 'satisfied' or 'very satisfied' to be seen by Joint Clinic staff rather than an Orthopaedic Surgeon (70%). The majority of patients (86%) were 'satisfied' or 'very satisfied' with the time they waited to be seen at the Clinic.

Interim interviews of GPs and staff

Interim evaluation interviews were conducted among staff and GPs. After three phases of the chain sampling

process, there were a total of 21 potential respondents, of which 16 were interviewed. These comprised six Orthopaedic Department or Joint Clinic clinicians, one allied health clinician, seven hospital administrative or managerial staff, one SDHB Māori (New Zealand's indigenous peoples) liaison, and one GP. Overall, data from the interim implementation evaluation indicated that the Joint Clinic had been implemented in close concordance with the proposed model and was well accepted by the key stakeholders, staff, and patients. Six major themes resulted: staffing, appropriate care provision, care coordination, promotion of the service, the Joint Clinic model and Hauora Māori (health and wellbeing of Māori).

Recurrent themes relating to staffing included high levels of confidence in the competence of personnel, and concerns regarding adequacy of allocated administrative staff time in light of heavier than expected additional workload. One aspect of the proposed model that was not implemented was the employment of "advanced physiotherapy practitioners". Instead, due to loss of the initial lead physiotherapist the Joint Clinic role was filled by an experienced physiotherapist without advanced practice experience or specific OA expertise. However a training programme had been provided. Staff surveys found that adequate leave cover for both the physiotherapist and the nurse were lacking. A physiotherapist was allocated and trained for 'back-up' cover, but became unavailable.

Some planned aspects were not concordant. It was found that some GPs wrote referrals of patients directly to the Joint Clinic, instead of following the existing protocol that referrals should be triaged by the orthopaedic surgeons, as any other referral would be. Also, clinic staff reported occasional difficulty in accessing orthopaedic surgeons for discussion regarding complex patients, leading to gaps in communication. The lead orthopaedic surgeon's time spent discussing cases with Joint Clinic staff had not been budgeted a priori.

Final implementation interviews

In the final implementation evaluation, six SDHB staff and seven GPs were invited to take part in one-on-one in-depth post-implementation interviews; all but one GP accepted and were interviewed. Six themes resulted from the data: clinic impacts, clinic value, access, knowledge and understanding of the clinic, communication, and the future of the clinic.

The main impacts of the Joint Clinic were generally seen as positive, as patients who previously would have been returned to their GPs were being seen at a secondary level. Providers commented that *"...it's absolutely plugged a huge gap..."* (SDHB staff), *"…instead of the referrals being triaged and sent back to the GP, not being seen at all... they're now being seen"* (SDHB staff) *"…more quickly, more efficiently, and more to the point...and help GP[s] to, to manage a long term problem"* (GP).

Interviewees had the impression that patients valued the service as well, and had benefited, at least psychologically, commenting that *"...patients do have the perception that they, that something's happening"* (GP), *and "All of them [patients] have had an improvement in their function. That doesn't translate into leading, needing less pain relief. It doesn't translate into not needing joint replacement. It does translate into believing that they haven't been abandoned by the system, into realising that they will recover from what is major surgery and holds considerable fear for most people still"* (GP).

The perception was raised that some may patients express initial disappointment because they didn't get to see an orthopaedic surgeon: *"...patients might feel fobbed off if the purpose of the Joint Clinic has not been explained to them"* (GP)*; "There are some patients that are initially quite upset or potentially frustrated with actually the fact that they're not seeing an orthopaedic doctor. However, I think with just a little bit of explanation of what that clinic actually involves, I think they realise that what the clinic has to offer is really, is really quite beneficial for them"* (SDHB).

The Joint Clinic was valued by the GPs interviewed, but the idea was raised that not all patients would gain substantial value from the clinic. While typical GP comments conveyed that they *"…think it's enormously valuable"* (GP), and *"Most of my patients would be enormously grateful for the care they receive. All of them have had an improvement in function"* (GP), some also commented that *"They like meeting the people, but it hasn't helped their hip"* (GP).

The SDHB staff interviewed generally agreed the programme was helping to meet unmet need, and there was good acceptance of the programme among the interdisciplinary team. *"It's helping the demand for FSA which it was, is also in excess of what we could supply"* (SDHB staff) and *"...the GPs are definitely coming on board too. Because, I mean on their referrals they're actually, quite a few of them are very proactive in writing that they think their patient would be suitable for the Joint Clinic"* (SDHB). The consensus was unequivocal that *"the allied health team do a really great job with it"* (Participant 2, SDHB) and*"There's a lot of trust and respect there within that relationship [between staff members]"* (SDHB).

Lack of clarity and understanding about the Joint Clinic was a noted weakness: *"I think the perceptions of what the Joint Clinic's trying to achieve or is actually doing differ across the primary care, secondary care sort of interface. So I'm not sure it's, people are totally clear about what's happening"* (SDHB). During interviews it was suggested that, to be successful in the future, the

Joint Clinic needed to increase its visibility, communicate its mission clearly to stakeholders, maintain its funding, and decrease attrition among physiotherapists and staff. Further details of the themes, subthemes, and additional data are available in the online-only supplemental material [see the appendices in Additional file 3].

Service level outcomes

Over 2 years, 358 new patients and 279 follow-ups were seen at the Joint Clinic, for a total of 637 patient visits during 2 years of operation (Table 1). Un-notified 'did not attends' (DNAs) were low with only 11 DNAs overall (3.8%) in the first year, and 16 DNAs (4.3%) in the second year.

The primary outcome of reducing unmet need for secondary care consultations and management in patients with hip or knee OA was achieved, with the proportion of GP referrals for hip or knee OA returned without offer of consultation reduced by 90%. Increased efficiency in its secondary care setting was demonstrated by reductions in overall (all-cause) referrals returned to GPs without consultation, despite an overall decrease in FSAs provided by the Department. The Joint Clinic resulted in an overall 5.7% increased capacity of the Orthopaedic Outpatient service to provide initial consultations compared with the year prior to implementation of the Joint Clinic. These changes were observed on a background of a decreased volume of referrals received overall (Table 2).

Table 1 Description of the patients and patient pathways of the first 2 years of Joint Clinic operation

	Total	
Patients referred to Joint clinic	376	
Declined	9	2.4%
Did not attend	9	2.4%
Patients attending Joint Clinic	358	
Patient characteristics		(of 358)
Age (SD)	76	9.8
Female	200	55.9%
Hip OA[a]	155	43.3%
Knee OA[a]	199	55.6%
Not OA[a]	19	5.3%
Met inclusion criteria[b]	339	94.7%
Joint Clinic management		
Initial consultation	358	95.2% (of 376)
1 follow-up	252	74.3% (of 339)
2 follow-ups	114	36.6% (of 339)
3 follow-ups	28	8.3% (of 339)
mean (SD) visits	2.1	0.91
Referred for FSA:		
Initial visit	59	16.5% (of 358)
Subsequent visit	74	
By another service	15	
Total	148	41.3%

GP General medical practitioner (family practice physician). [a]OA as the primary cause of hip or knee symptoms was the inclusion criterion for Joint Clinic management; sums to > 100 due to multisite OA. [b]OA of the hip or knee

Patient level outcomes have been reported elsewhere [30, 31]. In summary, approximately 60% of patients were managed non-operatively by the Joint Clinic, with a significant improvement (18% improvement on baseline Oxford score, $p = .0013$ for change by paired, 2-tailed t-test) noted in that group; the remaining 143/358 (40%) were referred for FSA, with 115 (80%) received or were listed for surgery [31]. At referral to Joint Clinic, no differences in age, sex, or patient-reported outcome measures were evident between those with hip versus knee OA, however mean BMI was higher in the knee OA group. Patients with knee OA improved significantly, on average, while patients with hip OA were more likely to deteriorate significantly and require surgery [30].

Cost-effectiveness

The net marginal unit cost for all Joint Clinic services and physiotherapy treatments provided in the Physiotherapy Outpatient Department decreased in each financial year from $550 per patient in year one to $384 per patient in the second year of operation, due to greater efficiency of clinician time allocated. The Joint Clinic operated significantly below budget in each financial year due to lower than budgeted total personnel costs.

Discussion

As the world's population ages, health care systems will come under greater pressure to meet the increasing burden of all musculoskeletal disorders, and OA in particular [1]. In New Zealand, the demand for joint replacement surgery is predicted to rise dramatically, placing substantial pressure on orthopaedic outpatient consultation services, which assess potential candidates for joint replacement surgery, and manage end-stage OA [3]. The results of this programme evaluation of an end-stage hip and knee OA Joint Clinic demonstrates that a service dedicated to meeting the unmet need in this area can be successfully implemented at the interface of primary and secondary care.

The proof-of-concept model for the Joint Clinic was supported by best-practice literature for OA care and by external experts [15, 17–20]. The Joint Clinic service delivery model was similar to others, such as those presented in the UK National Health and Australian healthcare systems [17, 32], and was founded on clinical evidence and experience from the Management of Osteoarthritis (MOA) Research Trial programme conducted locally at the University of Otago [10]. The MOA Trial was a randomised clinical trial

Table 2 Reductions in the number of patient referrals received by Orthopaedic Outpatients, number of First Specialist Assessments (FSAs) delivered, and number of referrals sent back to the GP without consultation: baseline and first 2 years of Joint Clinic operation

	Year 0[a]	Year 1	Change Year 0–1	Year 2 (cumulative total)	Change Year 0–2[b]
Referrals	2,078	1,584	−24%	1539 (3123)	−25%
FSAs	1,305	1,134	−13%	1267 (2401)	−8%
Referrals returned to GP	557	390	−30%	462 (852)	−24%
Referrals returned to GP [hip, knee OA only]	74	5	−93%	10 (15)	−90%

[a]the year prior to Joint Clinic implementation; [b]annual change = 1-([cumulative total/2]/year 0 total); *GP* General medical practitioner (family practice physician)

which included an economic evaluation [10–12]. This local evidence was supported by broader evidence for both effectiveness [10] and cost-effectiveness [11, 12]. The Joint Clinic structure also included several elements that are consistent with the Wagner Chronic Care Model, a model which aims to support patients with chronic conditions to self-manage their condition [21–23, 33, 34].

Government health policy [35], workforce recommendations [36], and local need [5] supported the rationale for the programme. The primary outcome of the Joint Clinic was intended to be reduction in unmet need for primary care referrals to secondary care. In Dunedin, the local unmet need is centred around access to orthopaedic FSAs and wait times for surgery, both of governed by the rationale for resource allocation [37]. This primary outcome was reduced by 90%. We have established that the new programme was successfully implemented as proposed, with the exception of the inability to retain the employment of "advanced physiotherapy practitioners". However the use of an experienced physiotherapist after provision of a training programme was successful and stakeholder satisfaction with the clinical staff was very high. We also were able to establish that the new programme was able to operate as planned and be well accepted by stakeholders. Dissatisfaction with access to orthopaedic surgeon FSAs was unchanged, post-implementation, from the high level (90%) reported pre-implemention, despite Joint Clinic facilitating access to FSA for 40% of patients who would otherwise have been sent back to the GP without consultation or advice. The qualitative data of the free-text responses support the interpretation that this reflects ongoing frustration with orthopaedic secondary care access problems more generally. Those data also indicated that the Joint Clinic was a helpful alternative, with some concerns also expressed that it was merely a 'delaying tactic' stalling access for patients who really required surgery/FSA.

The data indicated that the Joint Clinic was perceived to bridge the gap in care of those with OA of the hip and knee in a secondary setting satisfactorily, and provided welcome support for GPs in primary care. Referral volumes were lower than anticipated during implementation, and then increased to the intended capacity. The establishment of the Joint Clinic was observed to increase efficiency of orthopaedic surgeon appointment resources in the secondary care setting, in terms of increased provision of patient assessments overall, and shifting 'non-surgical' consultations from orthopaedic surgeons to Joint Clinic. The unit cost was lower than many other unit costs for non-pharmacological, non-surgical interventions for osteoarthritis reported in the literature, which indicate that the cost of intervention being more than recouped by savings in other health services over 1–2 year [12, 24, 38] . The SDHB concluded the Joint Clinic was a cost-effective use of resources and renewed programme funding. The service concluded the Joint Clinic was a cost-effective use of resources, and resolved to continue the new programme indefinitely.

Limitations of the evaluation include the uncertainty that results from background changes to referral patterns and Department capacity unrelated to the implementation of the programme. Overall referrals to the Department for FSA decreased in year 1, and recovered somewhat in year 2 but not to the level observed pre-implementation. The reason for this decrease cannot be concluded from the evaluation data, but may be due to ongoing education of GPs by the Orthopaedic Department on appropriate referral criteria and prioritisation criteria. We also cannot draw conclusions regarding the generalisability of the Joint Clinic to other regions or services with differing referral drivers, unmet need, or policy mechanisms.

Stakeholder interviews and survey data raised the concept of a primary care version of a Joint Clinic-like service, targeting OA earlier in the course of disease. The case for translating this service to a primary care setting is strong, to target OA earlier in the course of the disease. This approach is supported by research evidence [15, 17], indicating that conservative care is more effective in patients at earlier stages of OA progression [39, 40], and that early intervention can delay or prevent the need for joint replacement surgery [41, 42].

Conclusions

This programme evaluation has established that a physiotherapist-led clinic in a secondary care setting is feasible, effective in reducing unmet need, and is acceptable to all stakeholders. The Joint Clinic offers another

option for patients with OA of the hip and knee, and the services that provide care in a secondary setting. The service appears to provide a much-needed support for GPs in primary care. Thus the Joint Clinic services appear to be sustainable and there is the capacity for increased volume to extend the scope of the service.

Additional files

Additional file 1: Guidelines for the delivery of the outpatient physiotherapy intervention: The Joint Clinic (PDF 69 kb)

Additional file 2: The Joint Clinic programme logic model (PDF 59 kb)

Additional file 3: Appendices to the Methods and Results (PDF 571 kb)

Abbreviations

CPAC: Clinical Priority Assessment Criteria; FSA: First Specialist Assessment; GP: General Practitioner; OA: Osteoarthritis; QALY: Quality Adjusted Life Year; SDHB: Southern District Health Board; SMO: Senior Medical Officer

Authors' contributions

JHA conceived and led the study. JHA, CMC, HH and AW completed the literature review. CMC designed and distributed surveys, and analyzed the pre-implementation survey data. HH conducted interviews for the final evaluation, analysed and interpreted transcripts, conducted and analyzed the post-implementation surveys. CMC, KS, LH and DGJ comprised the core clinical team. DGJ, VM and CC led clinical service implementation and evaluation liaison. LH and KS completed much of the quantitative data collection. JHA, VM, CC and DGJ analyzed the quantitiative data. AW wrote the first draft of the manuscript. JHA edited the manuscript for intellectual content and wrote the final draft. All authors read and approved the final manuscript.

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Availability of data and materials

The data used and/or analysed during the current study are included in this published article and its supplementary information files [Additional file 3], and is also available from the corresponding author on reasonable request.

Ethics approval and consent to participate

Ethical approval was obtained from the Lower South Regional Ethics Committee (ethics reference LRS/12/EXP/018). Approval was also gained from Health Research South to undertake interviews with SDHB staff. Written informed consent was obtained from all participants (patients, healthcare professionals, and SDHB staff). In addition, consultation was completed with and subsequent approval received from the Ngāi Tahu Research Consultation Committee.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Health Policy & Economics

The Joint Clinic: Managing Excess Demand for Hip and Knee Osteoarthritis Referrals Using a New Physiotherapy-Led Outpatient Service

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ABSTRACT

Background: There are increasing problems with access to both outpatient assessment and joint replacement surgery for patients with hip or knee osteoarthritis.
Methods: Data were collected on all patients seen at the Joint Clinic over a 2-year period with minimum 12-month follow-up. Patients were assessed by a nurse and a physiotherapist, baseline scores and demographic details collected, and an individualized personal care plan developed. Patients could be referred for a first specialist assessment (FSA) if their severity justified surgical assessment.
Results: Three hundred fifty-eight patients were seen at Joint Clinic, of whom 150 (44%) had hip and 189 (56%) had knee OA. The mean age was 67.4 years and there were 152 men (45%) and 187 women (55%). The mean baseline Oxford score was 19.8 (standard deviation 8.2). Fifty-four patients were referred directly to FSA (mean Oxford score 13.0, standard deviation 6.7) and 89 after a subsequent review. The scores of patients referred for FSA were significantly worse than those managed in the Joint Clinic ($P < .001$). Of the 143 referred for FSA, 115 underwent or were awaiting surgery, 18 were recommended surgery but scored below prioritization threshold, and 10 were not recommended surgery. The Oxford scores of the 194 patients managed non-operatively improved from 22.0 to 25.0 ($P = .0013$).
Conclusion: This study shows that the Joint Clinic was effective as a triage tool with 93% of those referred for FSA being recommended surgery. This has freed up surgeon time to see only those patients most in need of surgical assessment.

With an ageing population there has been an increase in the incidence of hip and knee osteoarthritis (OA). Effective non-operative treatment may be an option for some patients especially those with less severe disease [1–3]. Total hip and knee replacements are very effective interventions for the management of end-stage OA [4]. An ageing population, confidence in the outcomes, and increasing demands from younger patients are leading to an increase in demand for these procedures [5–7]. As a consequence, public health services are struggling to cope [8,9].

In New Zealand, policy measures intended to balance demand with supply include financial penalties to District Health Boards (DHBs) if a patient is not seen for a first specialist assessment (FSA) within 4 months of the referral being accepted or if surgery is not provided within 4 months of offer to the patient. Prioritization scoring systems have been developed for patients recommended surgery at FSA with up to 40% of patients not qualifying for surgery in some DHBs and being returned to their general practitioner (GP) for further care and monitoring [10–12]. In order to achieve compliance referrals are also being returned to GP without the patient being seen due to capacity constraints. In this environment it is important that those patients seen at FSA are the most appropriate in terms of disease severity and potential to benefit. In

The program was funded as part of a wider program on improving patient flows in orthopedic surgery by the National Health Board (New Zealand).

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response to this, we developed a physiotherapy-led outpatient service for the assessment and management of OA of hip and knee [13].

The objectives of this study were to assess the effectiveness of the Joint Clinic in prioritizing those patients deemed most in need of FSA and optimizing non-operative management for those who may not need surgical assessment.

Methods

Our institution is the main hospital for a population of 200,000 covering one city of 125,000 and a sparsely populated area of 32,000 km^2. There are 10 orthopedic surgeons and 1 arthroplasty fellow who perform approximately 400 primary hip and knee arthroplasties per year.

The design and implementation of the clinic has been previously described [13]. It is staffed by a 0.5 full time equivalent (FTE) physiotherapist and 0.2 FTE orthopedic nurse. This nurse is also involved in the prioritization of patients wait-listed for hip or knee replacement [12]. An additional 0.5 FTE physiotherapist was appointed in outpatients to manage the increased load of outgoing referrals from Joint Clinic. Clinical oversight was provided by a senior orthopedic surgeon with an interest in arthroplasty. The program was funded as part of a wider program on improving patient flows in orthopedic surgery by the National Health Board.

The study reports on 358 patients seen in Joint Clinic for the initial 2-year period from June 1, 2012 until May 31, 2014. Patients referred by GP with hip or knee OA were triaged by an orthopedic consultant to Joint Clinic based on the details in the referral letter and radiographs. A full assessment including history and relevant physical examination was performed and further radiological investigations organized as required. Advice and counseling was given to the patients on their disease including optimization of analgesia. Referrals could be made for outpatient physiotherapy, dietitian advice, orthotic care, and occupational therapy. Patients could be fast tracked after discussion with the supervising orthopedic consultant to an FSA if they had severe symptoms. Patients with a very mild presentation could be discharged back to their GP. Patients referred with problems that were not OA of hip or knee were excluded from further analysis. Patients were offered a follow-up appointment at 6 months. At this stage, they could continue under Joint Clinic review, be discharged back to GP, or be referred for FSA if there had been a significant deterioration.

Details of initial demographics including age, gender, and diagnosis were noted. Baseline Oxford hip (OHS) and knee (OKS) scores were also collected. The OHS and OKS are widely used patient reported outcome measures, designed to assess joint-specific impairment of the hip and knee. In this study, the modified Oxford score was used, which contained 12 questions scored between 0 and 4, with 4 being the best outcome, thus yielding a total from 0 (worst outcome) to 48 (best outcome) [14].

The final outcomes including OHS and OKS completed at the patients' final Joint Clinic visit were collected until May 31, 2015 to give a minimum 12-month follow-up.

Statistical analysis was performed using Stata version 13 (College Station, TX). Analysis of variance and paired 2 tailed t-tests were used to compare continuous variables and chi-squared test was used for categorical data.

Results

Three hundred fifty-eight new patients referred with hip and knee joint OA were seen in the Joint Clinic. The median time to Joint Clinic appointment from referral was 18 days. Nineteen patients triaged to the Joint Clinic were found to not have OA of hip or knee and were excluded from subsequent analysis. Six of these patients had a spinal problem, of which 4 were referred for an FSA, and 13 had hip or knee problems that were not OA, of which only 1 had an FSA and subsequently underwent a knee arthroscopy. This left 339 patients with hip or knee OA (Fig. 1).

One hundred fifty patients (44%) had hip OA including 14 patients with bilateral disease and 2 with concomitant knee OA. One hundred eighty-nine patients (56%) had knee problems, of which 33 were bilateral. Details are given in Table 1.

Male patients presenting with knee OA were significantly older (69.2 years, standard deviation [SD 8.6]) than those men presenting with hip OA (65.0, SD 11.8) ($P = .012$). No further significant differences were observed in age, between genders, ratio of hips to knees, or initial Oxford score (Table 1).

Two hundred forty-six patients were seen on more than one occasion at Joint Clinic with a total of 401 follow-up visits. The average number of visits was 2.6 (range 2-4). Ninety-three patients only attended Joint Clinic on one occasion: 54 were referred directly for FSA, 23 self-discharged or failed to attend a follow-up appointment, 8 chose to go privately, 4 had died or had severe illness, and 4 were discharged directly to their GP.

The outcomes are summarized in Figure 1.

Fifty-four patients were referred to see a specialist after their first Joint Clinic visit. Their mean OHS and OKS of 13.0 were significantly worse than the remaining 285 patients ($P < .001$) (Table 2). A further 89 of these 285 patients (31%) were referred after subsequent Joint Clinic visits. The average wait for referral for this second group of patients was 309 days (SD 177) from their initial Joint Clinic appointment. Their Oxford scores at initial assessment were not significantly worse than those not referred for FSA ($P = .972$). However, by the time they were referred, they had deteriorated to the same level as the initial 54 and were significantly worse than those not referred for FSA ($P < .001$) (Table 2).

Of the 143 patients referred on for FSA (42% of all patients), 115 patients (80% of those referred for FSA and 34% of all patients) qualified for surgery, 18 (12.6%) were scored below threshold for surgery, and 10 were judged not to need surgery (7.4% of FSA). The conversion rate from Joint Clinic referral for FSA to recommendation for surgery was therefore 92.6%, with 80% of those referred from Joint Clinic qualifying for surgery after prioritization.

Patients with hip OA were significantly more likely to be referred for FSA than those with knee OA (81 of 150, 54% vs 62 of 189, 33%; chi-square 15.4, $P < .0001$). They were also significantly more likely to qualify for surgery than those with knee OA (70 of 150, 47% vs 45 of 189, 24%; chi-square 19.5, $P < .0001$).

Twenty-one patients (15 hips and 6 knees, 6% of all patients) had elected to go to the private sector either after initial Joint Clinic appointment or after an FSA and scoring below the threshold for surgery. Their initial scores were significantly better than those qualifying for public surgery ($P < .001$) (Table 2). A total of 136 patients (40% of whole group) had had surgery in either the public or private sector or were waiting for it with certainty of access to surgery within 4 months assured by the DHB.

At final follow-up, 194 of 339 (57%) patients seen at Joint Clinic with OA hip or knee were still being managed non-operatively. If the 54 patients who were referred for FSA at their initial appointment are excluded then 69% of the 285 patients who were treated and managed at Joint Clinic are still being managed non-operatively. The mean Oxford scores for these patients at last follow-up had improved by 3.1 points ($P = .0013$) (Table 2).

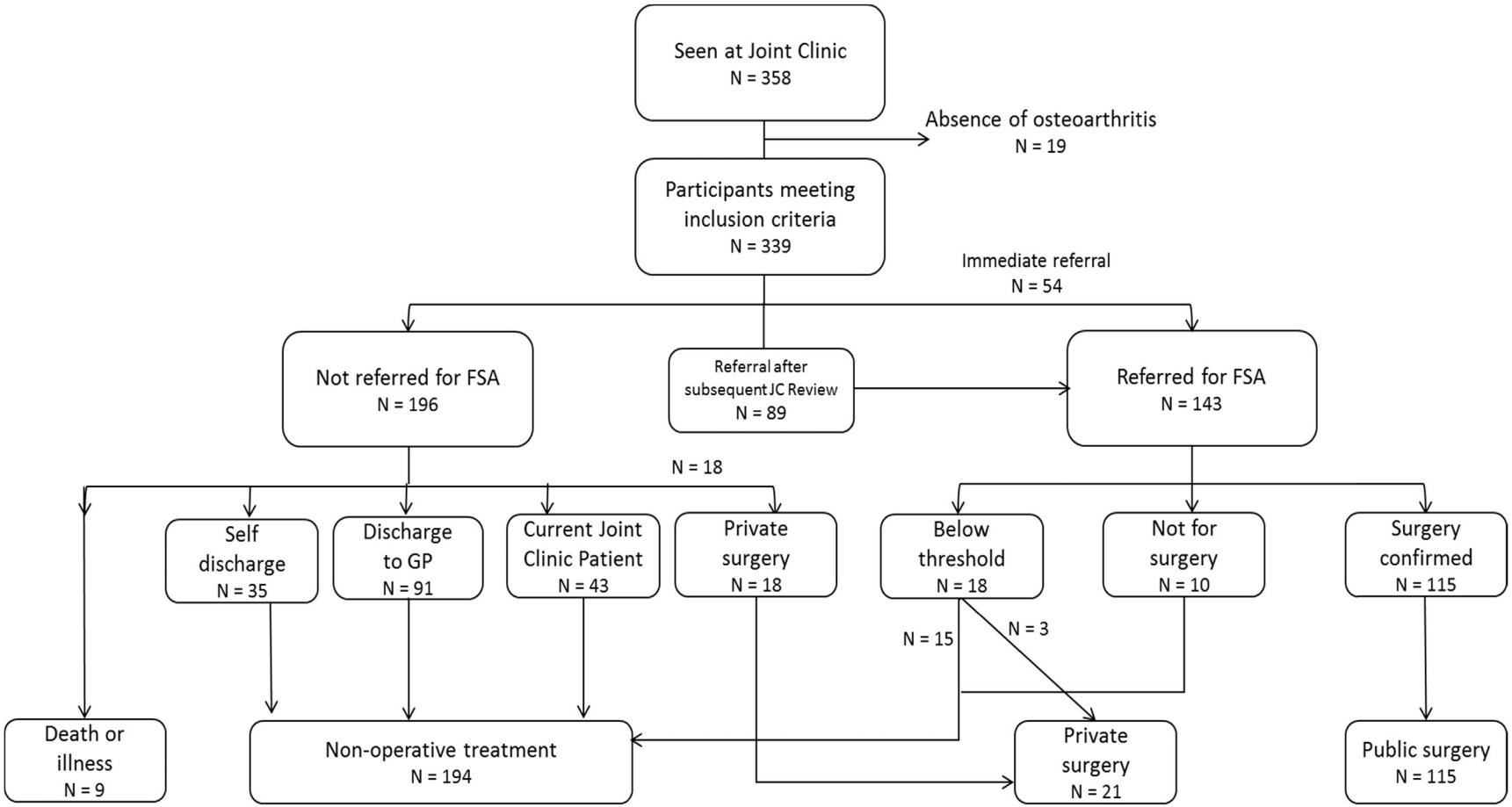

Fig. 1. Flow chart showing outcomes of all patients seen at the Joint Clinic. JC, Joint Clinic.

Table 1
Baseline Characteristics and Scores.

	All	Hips	Knees	*P* Value[a]
Number	339	150	189	
Age	67.4 ± 10.4	66.5 ± 11.5	68.1 ± 9.29	.155
Male	152 (45%)	66 (44%)	86 (46%)	
Female	187 (55%)	84 (56%)	103 (54%)	
Oxford score	19.8 (8.2)	20.3 (8.7)	19.4 (7.8)	.32

[a] Difference between hips and knees.

Discussion

This study has shown that the Joint Clinic model has been successful in helping prioritize and managing patients referred from primary care with a diagnosis of OA of the hip or knee. Previously, these patients would have either been returned to the referring GP without offer of assessment, or been seen in a specialist clinic after a lengthy wait.

Only 42% of patients seen were referred for FSA, with 196 specialist appointments potentially saved. Patients were only referred for specialist opinion if their symptoms were deemed severe enough to warrant surgery. The conversion rate from outpatient to recommendation for surgery was 92.6% and 80% of those referred qualified for surgery despite our need for explicit rationing.

Other studies have been less effective. Rogers et al [15] reported their experience with a multi-professional triage team assessing patients referred with lower limb problems. The correct diagnosis was made in only 47% and 69% of patients were subsequently referred to a hospital consultant with a significant delay compared with those referred directly.

Systematic reviews on Extended-Scope Physiotherapists (ESPs) in musculoskeletal triage and decision making have shown support for the clinical effectiveness in terms of diagnostic accuracy and satisfaction [16,17]. There is support for ESPs listing patients for surgery, with Parfitt et al [18] reporting 127 of 130 listed for hip replacement by the physiotherapist undergoing surgery. Griffiths et al [19] surveyed primary care-based ESPs referring onto secondary care and found an average 74% surgical conversion rate with a variation from 71% for mixed specialty team ESPs to 80% for individual sub-specialist ESPs. Desmeules et al compared an advanced practice physiotherapist's diagnosis with orthopedic surgeons in 120 patients referred for a hip (9%) or knee (91%) problem. Only 37 patients (31%) of the whole cohort were deemed in need of surgery by a surgeon with agreement in 33 (89%) by the physiotherapist [20]. Our results, with 93% of Joint Clinic referrals being recommended surgery and 80% of Joint Clinic referrals to FSA converting to surgery, compare favorably with those reports.

In our study, the Joint Clinic was explicitly set up to deal with hip and knee OA. All GP referrals to the department had to include relevant radiographs; therefore, the focus of the Joint Clinic assessment was more on education, non-operative management, and prioritization rather than diagnosis. Nevertheless, 19 patients triaged to the Joint Clinic were found not have OA of hip or knee with 6 having spinal problems.

The Oxford scores show that the most severe patients attending Joint Clinic were referred for FSA with scores of 13 compared with 22 points for those not referred. This difference is both clinically and statistically significant. The 18 patients who scored below threshold after FSA had a mean score of 20.6 which is not significantly different from those not referred. It is possible that these patients were dissatisfied with their Joint Clinic assessment and insisted on an FSA despite being less severe.

A basic principle of the New Zealand Ministry of Health's prioritization policy is to give patients certainty. Unfortunately, this may mean that 30%-40% of patients who recommended total joint replacement surgery do not qualify [10–12]. In this study, only 21 patients (6%) chose to pay for private surgery being advised at their Joint Clinic appointment that they would be unlikely to qualify or being scored below threshold. The rate of transfer to the private sector is low and similar to the rate of 5.9% seen in our previous study reporting on the outcomes of 374 patients returned to GP after being recommended surgery [21]. It may be related to a number of factors including poorer socioeconomic status, a historically good provision of public surgery, and awareness in the community of the problems with access to surgery so that patients who had the financial means may have been initially referred privately. The mean Oxford score of the patients who underwent private surgery was no different to those patients who did not get referred for FSA and significantly better than those undergoing public surgery. This suggests that many of those not referred for FSA would have had surgery recommended if there was no rationing within the public system, or were of sufficient means to self-fund.

There are limitations to this study. We cannot conclude whether the Joint Clinic model is generalizable to other settings. Although demand for hip and knee replacement is increasing and healthcare budgets are stretched, other countries or regions may not have the need for explicit rationing and prioritization that we face. For those reasons, the patients referred were of greater severity than anticipated when the clinic was being set up. This limited the options for effective non-operative management. However, 69% of those patients not referred directly for FSA were still being managed non-operatively at a minimum of 12 months after initial assessment with improvements in mean Oxford score of 3 points which may be clinically important [14].

Table 2
Change in Oxford Hip or Knee Score for Final Outcome Groups Defined in Figure 1.

Outcome	N	Initial Oxford Score (SD)	Latest Mean Oxford Score (SD)	Change in Mean Oxford Score	*P* Value
FSA after initial JC	54	**13.0 (6.65)**	–		
FSA after subsequent JC	89	18.2 (7.28)	**13.1** (6.89)	−5.1	<.001
Private[a]	21	20.8 (7.11)	17.1 (9.5)	3.7	.54
Current JC patients	43	21.0 (7.46)	23.5 (8.3)	2.5	.15
Discharge to GP[b]	116	22.5 (8.1)	26.0 (9.6)	3.5	.0049
Self-discharge	35	23 (7.87)	25.6 (8.3)	2.6	.7
All non-operative	194	22.2	25.3	3.1	.0013
Death/illness	9	21.1 (8.20)	24 (8.3)	2.9	.6

Scores in bold are all significantly worse than all other groups ($P < .001$).
JC, Joint Clinic.
[a] Includes 3 patients who had a specialist appointment, but were found to be under threshold.
[b] Includes 15 patients who had a specialist appointment, but were found to be under threshold and 10 who were not advised to have surgery.

It has been suggested by respondents during the implementation evaluation phase of this project that the Joint Clinic should sit within a primary care setting rather than in the orthopedic department [13]. All the interventions used by the Joint Clinic staff can be accessed in primary care. However, we believe that the close interaction among the orthopedic surgeons, lead physiotherapist, and the prioritization is a key contributor to the program's success. By keeping it within the orthopedic service, we have maintained control of the quality and quantity of referrals and avoided it becoming a depository for any patient with lower limb musculoskeletal pain. Both patients and GPs appear to have a strong acceptance of the hospital-based service.

A further criticism is that Joint Clinic is trying to stop patients from accessing surgery rather than expediting their referral. We are working within a financially constrained environment. However, we have found the clinic to be an effective part of our prioritization process. If a patient is seen and has severe disease they can be fast-tracked to an FSA and surgery, while patients without severe disease are diverted from taking up limited FSA resource. The time to Joint Clinic appointment from GP referral (median 18 days) is much shorter than the 4-month wait for an FSA if accepted.

Conclusion

This study shows that the Joint Clinic was effective as a triage tool. The diagnostic accuracy was excellent with the most severely affected patients being referred and 93% of those referred for FSA being recommended joint replacement surgery. This has freed up surgeon time to see only those patients most in need of surgical assessment. Over half of the patients triaged to Joint Clinic with hip and knee OA are still being managed non-operatively at minimum 12-month follow-up with a small improvement in patient reported scores.

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Primary Arthroplasty

Outcomes and Factors Influencing Response to an Individualized Multidisciplinary Chronic Disease Management Program for Hip and Knee Osteoarthritis

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ABSTRACT

Background: The objective of the study was to investigate the effectiveness of, and factors associated with, response to a chronic disease management program for patients with hip and knee osteoarthritis (OA).
Methods: Over a 2-year period (2012-2014), 218 patients (97 hip OA; 121 knee OA) were managed with an individualized program of interventions that could include education, physiotherapy, orthotics, occupational therapy, or dietitian referral. Changes in Oxford Hip Score or Oxford Knee Score and Short Form-12 (SF-12) Physical and Mental Component Summary Score (PCS, MCS) were analyzed by joint affected, both unadjusted, and gender and age adjusted. A further analysis also adjusted for body mass index.
Results: At mean 12-month follow-up, patients with knee OA had a statistically significant improvement in Oxford Knee Score and PCS, while patients with hip OA had a statistically significant deterioration in all 3 scores. There was evidence that these changes differed between joints for Oxford and PCS scores. Older age was associated with worse outcomes for Oxford scores. Higher body mass index was associated with worse outcomes for Oxford and PCS scores. Patients with hip OA (35%) were more likely to deteriorate to a clinically significant extent (5 points) for Oxford scores than those with knee OA. Gender was not associated with outcomes. Patients with hip OA (54%) were more likely than those with knee OA (24%) to have subsequently had surgery ($P < .001$).
Conclusions: Patients with knee OA were more likely to improve with a chronic disease management plan than patients with hip OA and efforts should be directed to them.

In New Zealand and elsewhere, increasing numbers of patients are being referred for assessment of hip and knee osteoarthritis (OA), and the demand for surgery is rising [1,2]. This is putting pressure on many public health-care systems. Hip and knee total joint arthroplasty (TJA) are very effective interventions for the management of end-stage OA. They have excellent long-term results and are cost-effective [3–6]. However, up to 15%-20% of patients may be dissatisfied with the outcome of knee arthroplasty [7]. It is important, therefore, that surgery is reserved for failure of nonoperative treatment which should be maximized and effective.

Nonoperative treatment may include pharmacological treatments, exercise and physiotherapy programs, dietary advice and weight loss, and education and advice [8–10]. There is evidence for the effectiveness of nonoperative measures in both knee and hip OA [9,11–13]. However, there is conflicting evidence on predictors of response to nonoperative treatment. Studies have been based on patient populations in differing settings, with varying interventions and variable severity of disease [13–15]. There has been a trend

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toward the development of a chronic disease management model with multidisciplinary input aimed at implementing an individualized program for the management of hip and knee OA [8,15]. This may have advantages in optimizing nonoperative care, reducing the need for surgery, or delaying it to a more appropriate time, setting expectations, prehabilitating patients and hopefully may result in fewer dissatisfied patients [7,12,15,16].

In our institution, we have limited capacity to match the increasing demand for both out-patient assessment and for surgery [17–19]. This led us to develop a physiotherapist- and nurse-led clinic to assess and manage patients with hip and knee OA [20,21]. We have shown this to be effective as a triage tool which has freed up surgeon time to see only those most in need of surgical assessment [21]. The main purpose of the clinic, however, was to maximize nonoperative management of patients referred with hip and knee OA.

The purpose of this study was to determine the effectiveness of and to identify factors associated with response to an individualized multidisciplinary nonoperative program for patients with hip or knee OA who were initially assessed as being below the threshold for surgery.

Patients and Methods

The joint clinic was developed as part of a wider program to improve orthopedic patient flows. After a literature review and consultation, a physiotherapist led out-patient clinic set within the Orthopaedic Department of our institution was developed [20,21]. Patients referred by their general practitioner (GP) for orthopedic consultation for symptomatic hip or knee OA were triaged by an orthopedic consultant surgeon to the joint clinic, on the basis of the referral letter and radiographs. At the joint clinic, patients were assessed and examined by a senior musculoskeletal physiotherapist and orthopedic nurse, and appropriate radiological investigations were performed. Patients were given advice and education on their OA including lifestyle modifications and optimization of analgesia. An individualized program of interventions was developed which could include referral to a dietitian, physiotherapist, occupational therapist, and/or orthotist to develop a chronic disease management program aimed at optimizing nonoperative treatment. Patients could be referred for specialist assessment for surgery either at initial appointment or at a follow-up appointment. Review appointments were offered at 6 months and then every 6 months according to the need. Patients could be referred back before 6 months if their condition had deteriorated.

The inclusion criteria for this study were all patients seen and subsequently reviewed at the joint clinic. Exclusions were patients referred for surgical assessment at the initial appointment, those who chose to go to the private sector, incorrect diagnosis of hip or knee OA, death or severe illness, and those discharged directly back to their GP because of a mild clinical presentation. Twenty-three patients self-discharged from clinic or failed to attend for planned follow-up at 6 months.

This study reports on 218 patients with hip or knee OA seen at the joint clinic over a 2-year period from June 5, 2012 to May 27, 2014 and reviewed at a mean 12 months from the first assessment. There were 121 (56%) patients with knee OA and 97 (44%) with hip OA (Table 1.).

Patient-reported outcome measures (PROMs) were collected at the initial assessment and at follow-up appointments at the joint clinic. The Oxford score is a condition-specific self-reporting instrument commonly used for OA of hip and knee. In this study, the modified Oxford score was used, which contained 12 questions scored between 0 and 4, with 4 being the best outcome, thus yielding a total from 0 (worst outcome) to 48 (best outcome) [22]. The SF-12 is a measure of general well-being, composed of physical component summary (PCS) and mental component summary (MCS) scores. The 2 component scores were computed from the responses to 12 questions yielding a range from 0 (worst outcome) to 100 (best outcome) [23].

Responders were defined as patients who had an improvement greater than the minimum clinically important difference (MCID) for each score. The MCID for the Oxford score may be as low as 2 points between groups. We used a change of 5 points as being a clinically important difference for an individual patient [22,24]. The change on SF-12 PCS has also been calculated as 5 points for patients after TKA [25]. No equivalent figures could be found for MCS in TJA, but an MCID of 4.4 points has been described following anterior cruciate ligament reconstruction [26]. Therefore, the MCID was also, conservatively, taken as 5 points for the MCS.

Statistical Analysis

Comparisons between groups were performed using Mann-Whitney *U* tests for continuous measures and chi-squared tests for categorical measures. Spearman's correlations were calculated for associations between continuous outcomes. Paired *t* tests were used to compare changes in each of the 3 outcomes from baseline to follow-up where the assumption of normally distributed changes was satisfied. Marginal homogeneity of changes using MCIDs for pairs of outcome scores was tested using the Stuart-Maxwell test.

Further analysis were performed using linear regression for continuous outcomes (changes in each of Oxford, SF-12 PCS, and SF-12 MCS scores) and multinomial logistic regression for clinically significant changes in these outcomes (with categories of worse, stable, and improved based on MCIDs of 5 as described previously). Analyses were performed including only joint and baseline outcome scores in the models and then adjusted for baseline age and gender. Additional analyses were performed adding baseline body mass index (BMI) to the model where this was available. Interactions between each independent variable (age, gender, BMI,

Table 1
Demographic Details and Baseline Scores for all Patients.

	All Patients	Male	Female	Male vs Female (*P*)	Hip	Knee	Hip vs Knee (*P*)
Number (%)	218	100 (46%)	118 (54%)		97 (44%)	121 (56%)	
Age (y), mean (SD)	67.6 (9.4)	67.6 (9.4)	67.7 (9.4)	.991	66.5 (9.7)	68.5 (9.1)	.177
BMI, mean (SD) for n = 89	29.8 (5.6)	29.7 (4.9)	29.9 (6.2)	.780	28.4 (5.2)	30.8 (5.6)	.048
OHKS, mean (SD)	21.1 (7.7)	20.8 (7.8)	21.4 (7.6)	.590	22.1 (8.2)	20.3 (7.2)	.104
SF-12 PCS, mean (SD)	33.4 (8.9)	33.8 (8.9)	33.1 (8.9)	.606	34.7 (9.6)	32.3 (8.1)	.056
SF-12 MCS, mean (SD)	50.1 (11.0)	50.0 (11.3)	50.3 (10.8)	.795	50.4 (10.9)	49.9 (11.2)	.453

P values are from Mann-Whitney *U* tests.
BMI, body mass index; OHKS, Oxford Hip or Knee Score; SF-12 PCS, Short Form-12 Physical Component Score, SF-12 MCS, Short Form-12 Mental Component Score; SD, standard deviation.

and baseline value) and joint were similarly examined in turn using likelihood ratio tests. As time until follow-up may affect responses, sensitivity analyses were performed by adding categories for time to follow-up to all adjusted models. All statistical analyses were performed using R version 3.4.3 and libraries as follows: nnet (7.3-12) for multinomial logistic regression, lmtest (0.9-35) for likelihood ratio tests, and multcomp (1.4-8) for general linear hypothesis estimates and tests. Standard model diagnostics were used for all models, including inspecting linear regression model residuals for normality and homoscedasticity. Two-sided $P < .05$ was considered statistically significant.

Ethics approval was given by the Lower South Regional Ethics Committee of the New Zealand Ministry of Health (ethics ref. LRS/12/EXP/018). All participants gave written informed consent.

Results

There were 218 eligible patients (mean age 67.6 years; 54% female) with hip (n = 97, 44%) or knee (n = 121, 56%) OA seen at the joint clinic on more than one occasion. The mean duration of follow-up was 365 days (median 353, range 52-1046 days). Oxford scores at baseline and follow-up were available for all 218 patients with 194 patients having complete SF-12 scores. There was no significant difference in age or gender balance between patients with hip or knee OA, although there was evidence of higher BMIs in the knee OA group. There was no difference in any of the PROMs at baseline between genders or between patients with hip or knee OA. Both SF-12 PCS and MCS scores were positively correlated with Oxford scores (Spearman's $P < .001$) but not with each other (Spearman's $P = .137$). Demographic details and baseline scores are summarized in Table 1.

Patients with hip OA deteriorated on all 3 outcome scores (Oxford 3.7 points, SF-12 PCS 2.2 points, and SF-12 MCS 3.3 points) ($P \leq .027$), while there was evidence of improvements in the Oxford (1.9 points) and SF-12 PCS (2.0 points) ($P \leq .022$) but not for the SF-12 MCS for those with knee OA (Fig. 1, Table 2).

There were no statistically significant difference in changes in scores for either gender or between genders with the mean differences in changes <1 point between males and females for Oxford, PCS and MCS.

In multivariable regression models, older patients were more likely to deteriorate on Oxford score regardless of the joint affected ($P < .001$). A similar association with age was seen on SF-12 PCS for patients with hip OA ($P = .002$) but not those with knee OA. Age had no significant association with change in SF-12 MCS.

BMI data at original presentation were only available for 89 patients. Worse changes were noted for the Oxford and SF-12 PCS for those with higher BMI (both $P \leq .027$) with no effect seen on SF-12 MCS. Adjusting for BMI when available resulted in similar findings to those described previously aside from slightly attenuating the age association for SF-12 for those with hip OA, which was no longer statistically significant ($P = .056$) and revealing a significant negative association between age and changes in SF-12 MCS scores ($P = .008$).

Patients with knee OA had a significantly greater change in Oxford ($P < .001$) and SF-12 PCS ($P = .009$) than those with hip OA, with a nonstatistically significant tendency for the same pattern with the SF-12 MCS ($P = .081$). These differences in the mean Oxford score between patients with hip and knee OA remained after adjusting for age and gender with the difference increasing to 5.5 points on Oxford and 3.4 points on SF-12 PCS. Similar results were found when also adjusting for BMI.

In total, 57 of 218 (26%) patients responded with an improved Oxford score $\geq$ the MCID of 5 points with similar proportions responding on the SF-12 PCS (27%) and MCS (25%). In contrast, 70 (32%) on Oxford, 53 (27%) on PCS, and 78 (40%) on MCS deteriorated by $\geq$ 5 points. There were more patients with knee OA who responded on Oxford score (35%) and fewer with a deterioration (21%) than those with hip OA (15%, 45%). However, a greater proportion of patients with knee OA (37%) deteriorated by > MCID for MCS than on Oxford (21%, Stuart-Maxwell test, $P = .007$) or PCS (23%, $P = .075$) (Fig. 2).

Associations between variables for worsening (score worsening by 5 or more points) or responding (scores improving by 5 or more point) were evaluated against remaining stable (Table 3). After adjusting for baseline characteristics, there was evidence for greater odds of deterioration on Oxford score in patients with hip OA compared with knee OA (adjusted odds ratio [aOR] 2.6, $P = .006$) and with increasing age (aOR 1.31/5 years, $P = .005$), while male gender almost reached significance (aOR 0.5, $P = .050$). Increasing age was also associated with higher odds for worsening >5 points on both SF-12 PCS (aOR 1.35/5 years, $P = .007$) and MCS (OR 1.24/5 years, $P = .021$).

Adjusted regression models were rerun adding a variable indicating duration of follow-up, based on categories of <10 months, (n = 101, 46.3%), 10-14 months (n = 75, 34.4%), and >14 months (n = 42, 19.3%). This made little change to the results in the

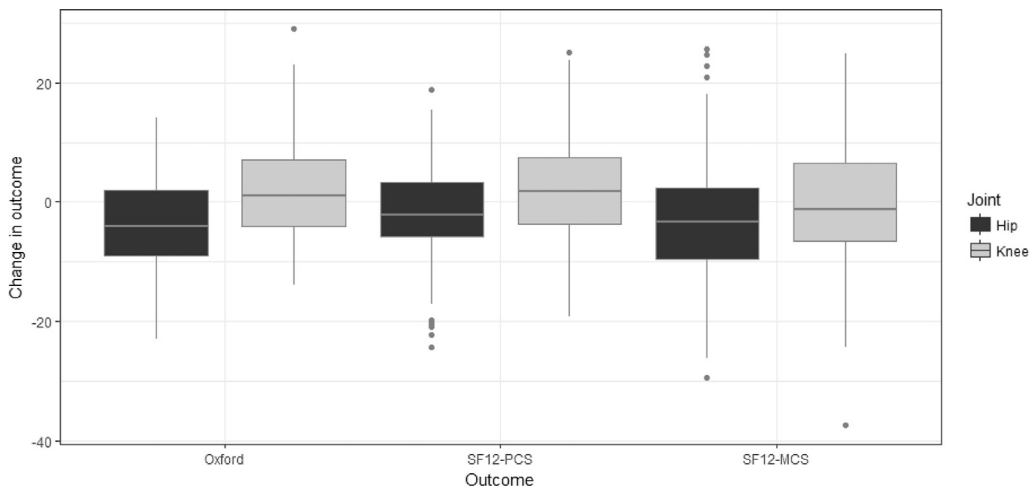

Fig. 1. Comparison of change in outcome scores for patients with hip and knee OA.

Table 2
Changes for Each Outcome Measure and Associations With These for Patient Characteristics.

	Outcome														
	Oxford					SF-12 PCS					SF-12 MCS				
	Pre	Post	Difference/ Slope	95% CI	*P* value	Pre	Post	Difference/ Slope	95% CI	*P* value	Pre	Post	Difference/ Slope	95% CI	*P* value
Unadjusted															
Hips	22.1	18	−3.7	−5.4 to −2.0	**<.001**	34.7	32.5	−2.2	−4.1 to −0.2	**.027**	50.4	47.1	−3.3	−5.7 to −0.8	**.010**
Knees	20.3	22	1.9	0.4 to 3.3	**.012**	32.3	34.3	2.0	0.3 to 3.7	**.022**	49.9	49.4	−0.5	−2.7 to 1.6	.625
Joints: hips compared with knees			−5.2	−7.3 to −3.0	**<.001**			−3.1	−5.3 to −0.8	**.009**			−2.5	−5.3 to 0.3	.081
Adjusted[a]															
Sex: male compared with female			−0.7	−2.8 to 1.4	.531			−0.1	−2.3 to 2.1	.924			−0.3	−3.1 to 2.6	.847
Age (per 5 y)			−1.0	−1.6 to −0.5	**<.001**								−0.4	−1.1 to 0.4	.346
Age (per 5 y) for hips								−1.4	−2.2 to −0.5	**.002**					
Age (per 5 y) for knees								−0.1	−1.0 to 0.8	.800					
Joints: hips compared with knees			−5.5	−7.6 to −3.3	**<.001**			−3.4	−5.6 to −1.1	**.004**			−2.6	−5.5 to 0.2	.073

Pre-post tests are from paired *t* tests; all other results are from linear regression models adjusting for baseline values and other variables as indicated. Bold text denotes statistical significance (*P* value < .05).
CI, confidence interval; SF-12 PCS, Short Form-12 Physical Component Score, SF-12 MCS, Short Form-12 Mental Component Score.
[a] Adjusted for all other variables in the model.

continuous or MCID models. Follow-up category was associated with outcomes on Oxford ($P = .022$), with worse outcomes for those with 10- to 14-month follow-up. For the Oxford MCID model, follow-up category was again significant ($P = .013$); the non-statistically significant tendency towards lower odds for hips responding became statistically significant (OR 0.44, 95% CI 0.20-0.95, $P = .036$). For SF-12 PCS, follow-up category was not statistically significant for the continuous model (Wald $P = .103$) but was for the MCID model (Wald $P = .035$), where the middle category had the lowest odds of improving. For SF-12 MCS, there was no evidence for any association with follow-up category (Wald $P = .769$ for continuous and $P = .525$ for the MCID model).

Eighty-one patients (37%) subsequently underwent surgery of which 9 patients had elected to self-fund in the private sector. Patients with hip OA (52 of 97, 54%) were significantly more likely than those with knee OA (29 of 121, 24%) to have undergone subsequent surgery (chi-square, $P < .001$).

Discussion

This study, in a secondary care setting, with patients referred by their GP for orthopedic surgical consultation, indicates that nonsurgical management with an individualized chronic disease management program can result in a clinically significant improvement in Oxford scores in 26% of patients while 32% deteriorate. Younger patients and those with knee OA were more likely to respond. Increasing age, increased BMI at baseline, and patients with hip OA had an increased risk of deteriorating. This is consistent with systematic review evidence that indicates that increasing age is predictive of long-term progression of hip and knee OA and that BMI was a strong predictor for long-term progression of knee OA [27,28].

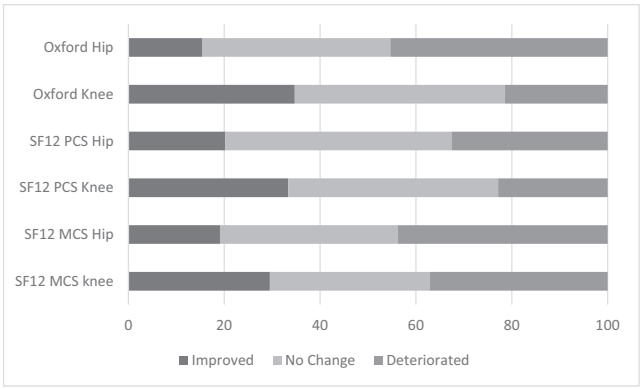

Fig. 2. Comparison between proportion of patients with hip and knee OA changing by greater than Minimum Clinical Important Difference (MCID) of 5 points from baseline to final visit on each score.

There is evidence to show that nonoperative treatment for both hip and knee OA can be effective even in patients referred for orthopedic assessment with advanced disease. Skou et al conducted a randomized clinical trial (RCT) comparing TKA with nonoperative treatment and showed that while TKA was more effective, the knee injury and osteoarthritis score in the nonoperative group improved by 16 points and only 26% of the group underwent surgery in the next 12 months [29]. In another RCT by the same group, a 12-week nonsurgical treatment program was compared with usual care in patients falling below the clinical threshold for total knee arthroplasty (TKA) [11].The knee injury and osteoarthritis score improved by 18.7 points and was 9.6 points higher than usual care. However, the proportion improving by at least 15% from baseline score (64% compared to 50%) was not significantly greater than the usual care group. In a large study of patients with mild knee OA, the odds ratio of improvement in pain was higher by a factor of 2 in patients receiving physiotherapy or multimodal treatment with radiographic severity not associated with improvement in pain [30].

Svege et al [12], in a randomized trial, compared education and exercise therapy with education alone in patients with symptomatic and radiographic OA of hip. Exercise delayed the median time to total hip arthroplasty (THA) from 3.5 to 5.4 years, with 41% survival of the native hip at 6 years compared to 25% in the education only group. However, Bennell et al [31] in a RCT comparing sham treatment with physiotherapy showed no improvement with the active program in patients with hip OA.

Some studies have included patients with hip and knee OA, though the effect of joint on response has been inconsistent. Weigl et al in a study of patients with hip (36%) and knee OA (64%) found that the joint affected was not a predictor. However, females, those without depression, taking complementary medicines and with low comorbidities had a response with 35% improving greater than

Table 3
Clinically Significant Changes for Each Outcome Measure (Change of 5 Points or More) and Associations With These for Patient Characteristics.

	OR for Worse	95% CI	*P* value	OR for Better	95% CI	*P* value
Oxford						
Unadjusted						
Joints: hips compared with knees	2.21	1.15-4.24	**.017**	0.50	0.24-1.02	.057
Adjusted[a]						
Sex: male compared with female	0.80	0.41-1.55	.509	0.50	0.25-1.00	.050
Age (per 5 y)	1.31	1.08-1.57	**.005**	0.94	0.78-1.13	.541
Age (per 5 y) for hips						
Age (per 5 y) for knees						
Joints: hips compared with knees	2.60	1.32-5.13	**.006**	0.50	0.24-1.05	.066
SF-12 PCS						
Unadjusted						
Joints: hips compared with knees	1.08	0.51-2.27	.835	0.58	0.28-1.19	.135
Adjusted[a]						
Sex: male compared with female	0.71	0.33-1.54	.388	0.76	0.38-1.54	.448
Age (per 5 y)	1.35	1.09-1.68	**.007**	1.07	0.88-1.31	.505
Age (per 5 y) for hips						
Age (per 5 y) for knees						
Joints: hips compared with knees	1.24	0.58-2.68	.581	0.60	0.29-1.24	.168
SF-12 MCS						
Unadjusted						
Joints: hips compared with knees	1.07	0.56-2.05	.837	0.54	0.23-1.24	.146
Adjusted[a]						
Sex: male compared with female	1.15	0.59-2.24	.680	0.90	0.39-2.07	.800
Age (per 5 y)	1.24	1.03-1.49	**.021**	1.13	0.89-1.42	.312
Age (per 5 y) for hips						
Age (per 5 y) for knees						
Joints: hips compared with knees	1.17	0.60-2.28	.646	0.57	0.25-1.34	.199

All results are from multinomial logistic regression models adjusting for baseline values and other variables as indicated. Bold text denotes statistical significance (*P* value < .05).
CI, confidence interval; OR, odds ratio.
[a] Adjusted for all other variables in the model.

18% on baseline Western Ontario MacMaster Osteoarthritis Index (WOMAC) at 6 months [14]. Angst et al [13] reported on patients with hip and knee OA who were admitted for 3 weeks of inpatient rehabilitation and found no difference between hip and knee with a significant improvement of 10 points on WOMAC score for each at discharge. The improvements seen on SF-12 for both hip and knee were small with only PCS knee (2.7 points) reaching statistical significance. In our study, we saw a similar improvement in PCS for patients with knee OA, whereas those with hip OA deteriorated significantly on both PCS and MCS.

Eyles et al [15] reported their results using a similar chronic disease management program at 6 months, in a setting in which the majority of patients (90%) came from surgical waiting lists. Twenty-eight percent of the whole group was classified as responders (an improvement of minimum 9 points and 18% from baseline WOMAC). Patients with knee OA were more likely to respond than those with hip OA (OR 1.9), while males were less likely to respond than females (OR 0.55). Age and BMI were not predictors of a response in their study. However, in a further study, they concluded that variables that predict worsening of OA following a chronic disease management program remain largely unknown [32]. We found very similar ORs for response for joint affected and gender in our study but at longer follow-up of 1 year. The relationship with gender did not quite reach significance, however.

Our response rate of 26% is similar to these reports despite there being a higher proportion of patients with hip OA (44%) in this study than in others (15%-36%) [13–15,32]. Our response rate for patients with OA knee was 35%. We did not see improvements in mean scores reported in previous studies. The follow-up period was for 1 year on average, and initial improvements may have been lost as the disease progressed. The patients all had radiologically proven OA and had been referred for assessment of surgery which may explain the relatively low responder rate. We believe that the difference demonstrated between hip and knee OA bears out our clinical impression that patients with knee OA can improve with nonoperative treatment such as a muscle strengthening program and weight loss, while those with established hip OA tend to progress. We found changes with the condition-specific Oxford score tended to be greater than the more generic SF-12. As expected, the PCS tended to mirror the changes in Oxford score for both the hip and knee groups. The higher proportion deteriorating and lower proportion improving on MCS for those with knee OA suggests that while there may be some improvement in physical function, patients may not be satisfied.

We have problems with access to both surgical consultation and joint arthroplasty. The joint clinic was developed to help improve access by prioritizing those patients most in need of surgical assessment and to optimize nonoperative management of those with less severe symptoms. It is effective at triaging patients with 93% of patients referred on to a specialist being recommended surgery [20]. The clinical threshold score for surgery may vary in different centers and countries [33]. During the same period, in our center, the average preoperative OKS was 11.1 and postoperative OKS was 39.8 [34]. The patients in our study were assessed as not requiring or qualifying for surgery at their initial appointment and are at the milder end of the spectrum of symptoms that we see. However, they may have been recommended surgery elsewhere if access was better. Had they been able to access surgery the potential improvement of 15-20 points from their baseline score is significantly more than the relatively small changes seen as a result of the joint clinic interventions. While we believe that the joint clinic helped prepare patients for surgery, it was outside the scope of this study to look at outcomes following subsequent surgery.

Up to 20% patients are dissatisfied or unsure following TKA [7]. Clement et al [35] reported that meeting patient expectations and an

increase in OKS of more than 12 points or a postoperative score of >31 was associated with satisfaction. Scott et al [7] reported that poorer preoperative MCS scores have been shown to be predictive of poor outcomes after TKA with a mean drop of 2 points in the dissatisfied group with an increase of 1.9 points in the satisfied patients. In this study, we saw no significant change on MCS for those with knee OA, but patients with hip OA showed a mean drop of 3.3 points. Forty percent of all patients deteriorated by 5 points or more on the MCS which is likely to be a clinically relevant amount.

This is an observational study investigating the effectiveness of and potential associations with patient characteristics and response to an individualized multidisciplinary chronic disease management program for hip and knee OA. A strength of the study is that both a condition-specific PROM and a general health PROM were collected, including a mental component score. There were similar proportions of patients with hip and knee OA who were well matched with respect to age, gender, and baseline scores. Other studies have relatively low numbers of patients with hip OA which may have led to inadequate power to detect the differences we found. Follow-up was at an average of 1 year rather than 6 months or less, and patients were not taken from the surgical waiting lists which might influence patient expectations. The joint clinic was set in a real-world clinical setting and thus is potentially generalizable and may offer benefit for other health-care systems that face increasing demand.

A weakness of the study is that there was no single intervention offered, as treatment was individualized. Our BMI data were incomplete, and we did not record weight change. There was no control group to assess the effectiveness of the program. We may, therefore, be reporting the natural history of hip and knee OA. However, we believe that these results are still relevant. They might help to identify patients who are likely to respond or deteriorate following nonoperative treatment at 1 year. It is desirable to concentrate efforts on those patients in whom there is a reasonable expectation that nonoperative treatment will lead to a clinically relevant improvement that may postpone or even avoid the need for surgery. Conversely, there is little point in prolonged nonoperative treatment that delays surgery for patients who are most likely to deteriorate.

Conclusion

Nonsurgical management for patients with hip and knee OA with an individualized chronic disease management program can result in a clinically significant improvement in 26% of patients while 32% deteriorate. Factors associated with a response were patients with knee OA and younger patients. Increasing age and patients with hip OA were associated with an increased risk of deteriorating with over half the patients with hip OA progressing to surgery compared with 24% of patients with knee OA. This suggests that programs such as this may be better directed toward younger patients and those with knee OA. This model may work better for patients with less severe osteoarthritis.

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Joint Preservation & Non Arthroplasty

The Outcomes of Nonoperative Management of Patients With Hip and Knee Osteoarthritis Triaged to a Physiotherapy-Led Clinic at Minimum 5-Year Follow-Up and Factors Associated With Progression to Surgery

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knee arthroplasty
physical therapy
nonoperative treatment

ABSTRACT

Background: The purpose of this study is to determine outcomes of a nonoperative treatment service for hip and knee osteoarthritis (OA), the "Joint Clinic," at minimum 5-year follow-up, and investigate factors that may influence progression to joint replacement surgery.
Methods: This is an observational cohort study of 337 patients with hip (n = 151, 45%) or knee OA (n = 186, 55%) seen at the Joint Clinic, at 5-7 years of follow-up. Kaplan-Meier survival curves were used to determine survivorship of the affected joint and Cox regression used to determine factors associated with time to surgery.
Results: At mean 6-year follow up, 188 (56%) patients had undergone or were awaiting total joint arthroplasty, 127 (38%) were still being managed nonoperatively, and 22 (7%) had died without having surgery. Patients with hip OA were more likely to have required surgery (111/151, 74%) than patients with knee OA (77/186, 41%) (chi-square = 33.6, $P < .001$). The 7-year surgery-free survival for hip OA was 23.7% and knee OA 55.9% ($P < .001$). Factors associated with increased likelihood of surgery were joint affected (hip, hazard ratio [HR] 2.80), Kellgren-Lawrence (KL) grade (KL 3, HR 2.02; KL 4, 4.79), and Oxford Hip/Knee Score (HR 1.34 for each 5 points worse at baseline).
Conclusion: More than 50% of the patients referred to secondary care with mild-moderate knee OA may not need surgery at 7 years. Patients with hip OA and those with severe radiographic changes are more likely to require surgery and should not be delayed if there is not an adequate response to conservative measures.

Total hip arthroplasty (THA) and total knee arthroplasty (TKA) are highly effective interventions for advanced stage osteoarthritis (OA). The demand for arthroplasty is increasing which is putting pressure on hospital services, and despite the success of THA and TKA not all patients are satisfied and the complications of surgery may be major [1,2]. Therefore it is important that nonoperative options should be exhausted before surgery [3,4].

There is strong evidence to suggest that nonoperative treatment can be beneficial in patients with OA and may reduce or delay the need for surgery [5–7]. A multidisciplinary chronic disease management approach has been recommended [3,4]. However, many of these studies have relatively short-term follow-up and it is less clear what the long-term results are of nonoperative treatment. Studies have shown that the time to surgery may be delayed [7] or need for surgery reduced, with 54% of patients not progressing to surgery at 6 years after initial consultation [8]. However, these reports are from countries with different healthcare systems and the

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severity of presenting patients' symptoms and disease and the threshold to access THA and TKA may vary. If these results can be reproduced in other public health systems that have capacity constraints, there would be important benefits.

In New Zealand (NZ), as in other countries, the incidence of hip and knee OA has been rising due to the aging and growing population, and increasing prevalence of obesity [9,10]. Consequently, there is an increasing demand for both orthopedic outpatient appointments (the initial of which, for each patient, is termed the First Specialist Assessment [FSA] in our health service) and THA and TKA in the public sector [11,12]. The expectation from the NZ Ministry of Health is that a patient should be seen within 4 months of acceptance of a referral. Breaches of this target are monitored with the potential for financial penalties to the District Health Board (DHB). However, if there is insufficient capacity to meet this target, the DHB is allowed to decline the referral to prevent breaches. Similarly, if a patient is recommended surgery but it cannot be performed within 4 months, then they can be declined and returned to their general practitioner (GP) for ongoing care. This has led to the development of scoring systems designed to prioritize patients and the concept of a "financial threshold" score for surgery [13]. The Joint Clinic (JC) was set up in 2012 to improve access to specialist consultation and maximize nonoperative treatment by meeting unmet demand through a multidisciplinary chronic disease management approach [14]. An audit of the first 2 years of patients seen at the JC showed that 69% of patients were still being managed nonoperatively [15]. Patients with hip OA were more likely to have undergone surgery than those with knee OA and patients with knee OA were more likely to have a clinically significant improvement [15,16].

The purpose of this study is to determine long-term outcomes following nonoperative treatment coordinated through the JC. If the early results are maintained at 5 years this would be clinically important both for patients and for an over-stretched public health service. The primary outcome of our study is to determine the proportion of patients that are still being managed without surgery. Secondary outcomes are to determine what factors may be associated with requiring surgery or not at minimum 5-year follow-up.

Methods

This is an observational study of 339 patients seen at the JC between June 2012 and May 2014, with a mean follow-up period of 6.1 years. Patients with hip or knee OA referred by their GP to the orthopedic department were triaged to JC for evaluation. An individualized management program was developed which included advice on their condition, optimization of analgesia, and referral for an outpatient physiotherapy OA program, occupational therapy, dietitian advice, or orthotic management where indicated [14]. Patients could be referred for FSA if their presentation was severe enough. Patients were reviewed every 6 months until they were discharged back to GP if their symptoms were stable, or they had deteriorated to the extent that they needed referral for surgical assessment. Patients with bilateral disease were included and those referred with both hip and knee OA were classified by the most symptomatic joint at baseline. Two patients of the 339 had been referred with painful joint replacements and were excluded. This left 337 eligible patients with hip OA (n = 151, 45%) and knee OA (n = 186, 55%) seen at the JC during its first 2 years of operation.

Baseline data including age, gender, body mass index (BMI), and joint affected were collected at initial assessment. Radiographic stage at presentation was assessed using the Kellgren-Lawrence (KL) system [17]. Patient-reported outcome measures (PROMs) were gathered at initial assessment and at subsequent follow-up visits. The Oxford Hip and Knee Scores (OHS, OKS) include 12 questions on activities of daily living designed to assess pain and function of the hip or knee. The scores are graded from 0 being most severe to 48 being no problems with the joint [18]. The Short Form 12 (SF-12) was also collected which allowed calculation of the physical component score (PCS) and mental component score (MCS) [19].

Subsequent patient outcomes including PROMs were determined by accessing a combination of Orthopedic Department databases, electronic patient records, and radiology systems to provide details of any completed surgery. This was cross-referenced with the NZ National Joint Registry to find details of surgery performed elsewhere in NZ [20]. A questionnaire was also sent out to patients to confirm their current status with 213 of 308 (69%) surviving patients responding. The final outcome with respect to surgery was determined for all patients.

Kaplan-Meier curves were calculated to determine survivorship of the affected joint with the end point of joint replacement. Univariate and multivariate Cox regression analyses were performed to investigate the relationship among baseline variables including joint affected, radiographic grade, age, gender, BMI, and PROMs, and time to surgery. Statistical analysis was performed using R version 3.6.0 [21]. Statistical significance was taken as $P < .05$.

Results

The hip and knee cohorts were very similar in baseline characteristics with the only statistically significant difference being a higher BMI in patients with knee OA (Table 1). There were fewer patients of healthy weight (BMI <25 kg/m^2) with knee OA. In total, 188 (56%) of the 337 patients either had surgery (186) or were waitlisted for surgery (2 patients). Twenty-two patients (7%) had died without having surgery, of which 2 patients (1 hip, 1 knee) were waitlisted but died before surgery. Seven patients who had undergone THA (4) or TKA (3) had died. One hundred twenty-seven (38%) of all patients were still being managed nonoperatively.

A higher proportion of patients initially presenting with hip OA have had or are awaiting surgery (111 of 151; 74%) compared with patients with knee OA (77 of 186; 41%, $P < .001$). This includes 1

Table 1
Descriptive Statistics of the Sample.

	Knee OA	Hip OA	Hip OA vs Knee OA Comparison *P*-Value
Total, n	186	151	
Age (y)	68.1 (9.2)	66.4 (11.6)	.134
Gender (female), n (%)	102 (54.8%)	85 (56.3%)	.875
BMI (kg/m^2)	31.5 (6.1)	28.8 (5.3)	<.001
Healthy weight, n (%)	11 (10.4%)	28 (25.5%)	<.001
Overweight, n (%)	40 (37.7%)	44 (40.0%)	.129
Obese, n (%)	55 (51.9%)	38 (34.5%)	.388
K-L grade, n (%)			.231
Grade 1	18 (9.7%)	7 (4.6%)	.096
Grade 2	50 (26.9%)	35 (23.2%)	.452
Grade 3	88 (47.3%)	80 (53.0%)	.381
Grade 4	30 (16.1%)	29 (19.2%)	.388
Health-related quality of life scales			
Oxford Hip/Knee Score	19.5 (7.8)	20.3 (8.7)	.356
SF-12 PCS	31.9 (8.0)	33.2 (9.2)	.184
SF-12 MCS	48.4 (11.9)	48.8 (11.9)	.778
Time to final follow-up (y)	6.1 (0.6)	6.1 (0.6)	.809
Death prior to surgery	11 (5.9%)	11 (7.3%)	.661

Cells are reported as mean (SD) unless otherwise specified.
OA, osteoarthritis; BMI, body mass index; K-L grade, Kellgren-Lawrence radiographic OA grade; SF-12, Short Form 12; PCS, Physical Component Summary; MCS, Mental Component Summary.

patient awaiting surgery in each group. Two patients initially seen with knee OA have subsequently developed hip OA and undergone THA.

Of the 127 surviving patients that have not had surgery (29 hip OA, 98 knee OA), 25 have had an FSA. Nine were advised surgery but scored below the financial threshold and returned to GP care and 16 were not recommended surgery. Eight patients who had been discharged from JC were re-referred but assessed as being below the threshold for surgery and therefore not referred for FSA. The remaining 94 patients (24 hips, 70 knees) have either been discharged back to their GP (71) or self-discharged from JC due to self-managing the disease at the time of review (20). Three patients were too ill to consider surgery (Fig. 1). Follow-up PROMs were available for 101 of the 127 (80%) patients in the nonoperative group. For patients with hip OA, the mean OHS (change from baseline) was 25.3 (−0.2), SF-12 PCS 35.2 (−0.2), and MCS 43.9 (−2.9). For patients with knee OA, the corresponding scores were OKS 24.8 (+3.1), SF-12 PCS 35.0 (+2.1), and MCS 48.7 (−1.9). For patients with hip OA, 25% had improved and 36% deteriorated by 5 points or more on OHS/OKS at latest review. The corresponding figures for patients with knee OA were 42% improved and 24% worse.

A Kaplan-Meier survival curve censoring patients when they underwent surgery or died showed that 46% of all patients at 5 years and 41.6% at 7 years had not undergone surgery. There was a significantly higher chance of not requiring surgery in patients with knee OA (55.9% at 7 years) than those with hip OA (23.7% at 7 years) (Fig. 2). The radiographic grade of OA was associated with the likelihood of undergoing surgery with a statistically significantly greater risk of surgery with increasing K-L grade (Fig. 3). When the THA and TKA groups were analyzed separately (Fig. 4), there was little difference in survival for K-L grade 3 and 4 for hip OA, with similar proportions surviving without surgery at 7 years (grade 3, 14.3%; grade 4, 11.6%). However, for knee OA there was a strong association with K-L grade—those with grade 4 at baseline had progression rates close to those of patients with advanced hip OA (20% survival at 7 years), but those with grade 2 or 3 had a lower rate of progression to TKA.

Univariate and multivariate Cox regression (Table 2) revealed that patients with hip OA were significantly more likely to undergo surgery than those with knee OA (multivariate hazard ratio [HR] 2.80, $P < .01$). K-L radiographic grade was strongly associated with likelihood of surgery on both univariate and multivariate Cox regression (Fig. 3, Table 2) with a HR of 2.02 for K-L grade 3 and 4.79 for grade 4 (multivariate model). Age was significant in the univariate model only, with an 8% increase in risk of progressing to surgery for each additional 5 years of age at baseline. Gender and BMI were not significant predictors of the likelihood of surgery. The OHS/OKS was significant on both univariate and multivariate models with a 34% increase in risk for each 5 points worse at baseline. SF-12 PCS score was significant only in the univariate model, with an increase in risk of 16% for each 5 points worse at baseline.

When patients with hip and knee OA were analyzed separately, in the multivariate model, patients with knee OA K-L grade 3 and 4 and worse SF-12 PCS were significantly more likely to undergo

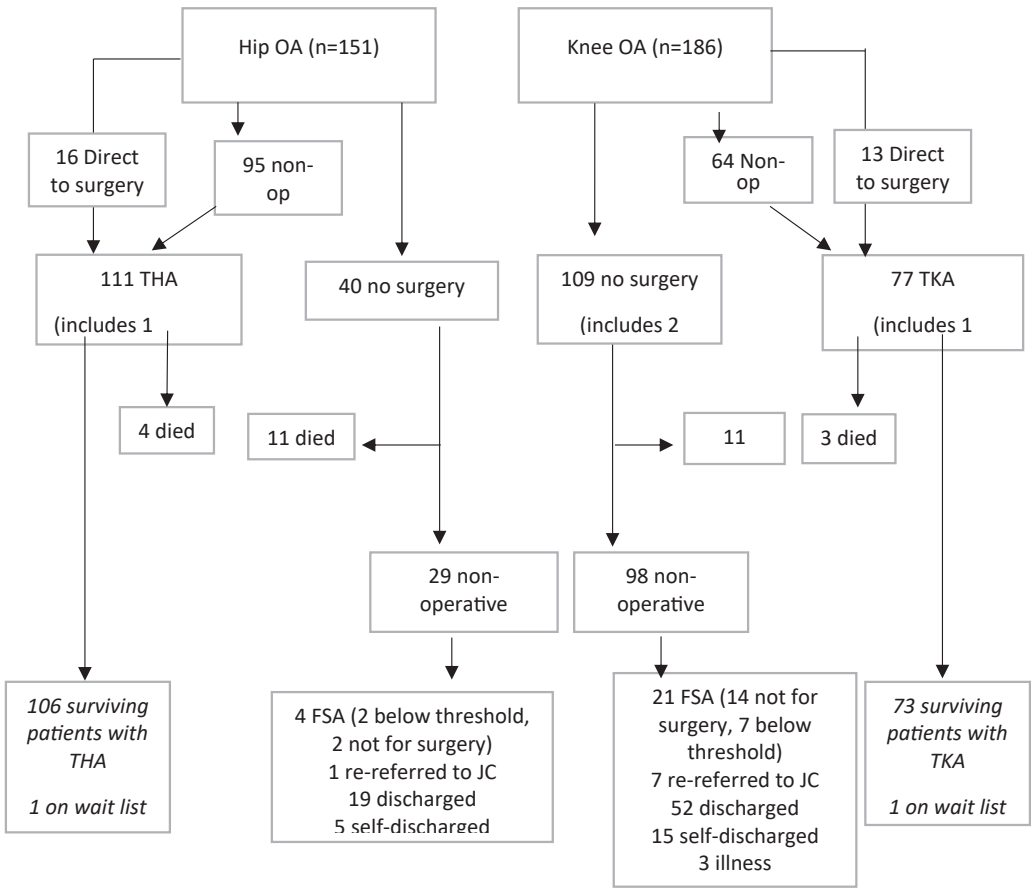

Fig. 1. Flow chart showing outcomes of patients seen at Joint Clinic. OA, osteoarthritis; JC, Joint Clinic; FSA, First Specialist Assessment; THA, total hip arthroplasty; TKA, total knee arthroplasty.

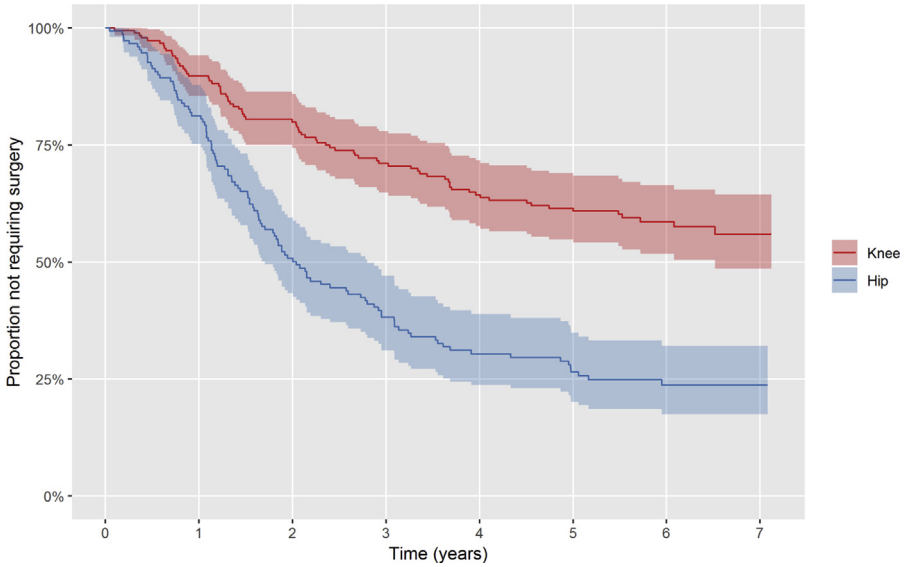

Fig. 2. Kaplan-Meier curve showing survival of joints not requiring surgery compared to patients with hip and knee osteoarthritis. Survival (%, 95% confidence intervals) at 5 years: knee = 61.5% (54.8-69.0), hip = 26.5% (20.1-34.9); 6 years: knee = 58.6% (51.7-66.4), hip = 23.7% (17.5-32.1); and 7 years: knee = 55.9% (48.5-64.4), hip = 23.7% (17.5-32.1).

surgery. For patients with hip OA, K-L grade 4, a worse OHS or a higher SF-12 MCS were significant (Table 3).

Discussion

To our knowledge, this is the largest longitudinal cohort study of nonoperative treatment of hip and knee OA with minimum 5-year follow-up. We have shown that 44% of the patients initially seen at the JC have not undergone surgery at 5-7 years of follow-up. Patients with knee OA (59%) were more likely to have not undergone surgery than those with hip OA (26%). As expected, compared with the 2-year results [15], a greater proportion of patients have progressed to surgery, but the differences between hip and knee are maintained. The baseline factors associated with requiring surgery were joint affected, that is, hip rather than knee, more advanced radiographic grade, and worse baseline OHS/OKS. The group of patients with knee OA who were still being managed nonoperatively had small gains in mean OKS and SF-12 PCS compared with baseline which may not be clinically relevant, while the group with hip OA who were still being managed nonoperatively, had no change.

A similar Australian study from Dabare et al [8] of 247 patients reported 54% of patients not requiring surgery at 6 years. The patient characteristics are comparable between the studies, but their cohort included only 80 patients (30%) with hip OA compared to 151 (45%) in this study. Patients in the Australian study were referred either from orthopedic outpatients or the community because they were not in need of surgery and there was ready access to surgery for patients that needed it as soon as nonoperative treatment was determined to not be providing an improvement. In

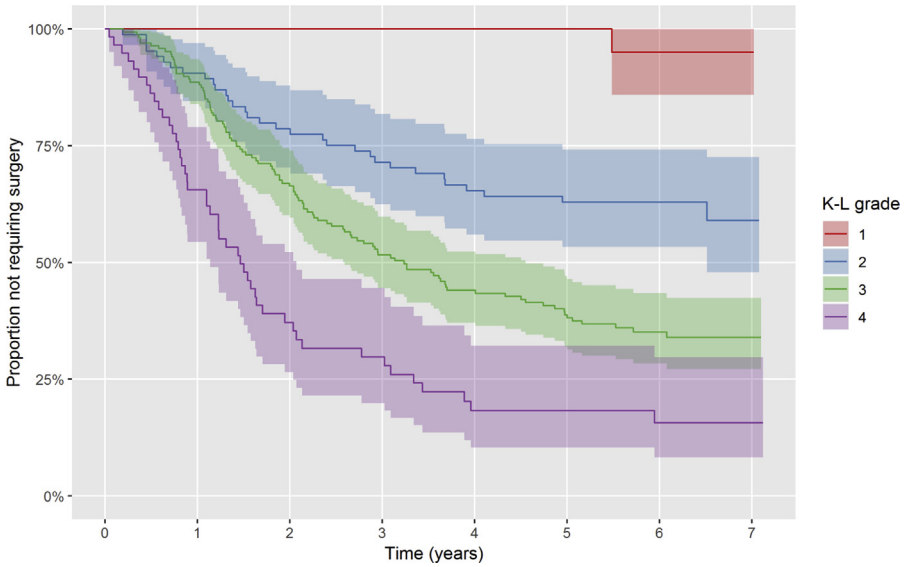

Fig. 3. Kaplan-Meier survival curve for proportion not requiring surgery by Kellgren-Lawrence grade at baseline. Survival (%, 95% confidence intervals) at 5 years: grade 1 = 100.0% (100.0-100.0), grade 2 = 62.9% (53.4-74.2), grade 3 = 38.8% (32.0-47.1), grade 4 = 18.3% (10.4-32.1); 6 years: grade 1 = 95.0% (85.9-100.0), grade 2 = 62.9% (53.4-74.2), grade 3 = 35.1% (28.4-43.5), grade 4 = 15.6% (8.2-29.7); and 7 years: grade 1 = 95.0% (85.9-100.0), grade 2 = 59.0% (47.9-72.6), grade 3 = 33.9% (27.1-42.4), grade 4 = 15.6% (8.2-29.7).

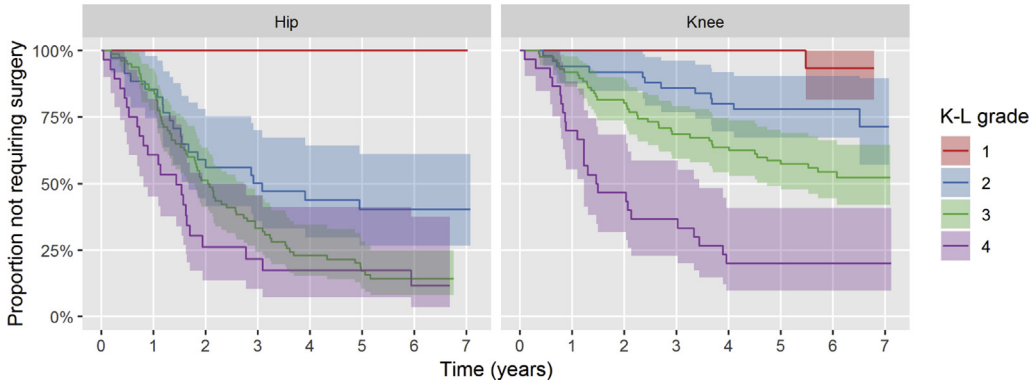

Fig. 4. Kaplan-Meier survival curve for proportion not requiring surgery by Kellgren-Lawrence grade at baseline by affected joint. Survival at 5 years (95% CIs): knee: grade 1 = 100.0% (100.0-100.0), grade 2 = 78.0% (67.3-90.4), grade 3 = 58.7% (49.1-70.2), grade 4 = 20.0% (9.8-40.9); hip: grade 1 = 100.0% (100.0-100.0), grade 2 = 40.4% (26.7-61.3), grade 3 = 17.3% (10.6-28.3), grade 4 = 17.4% (7.4-41.2); 6 years: knee: grade 1 = 93.3% (81.5-100.0), grade 2 = 78.0% (67.3-90.4), grade 3 = 54.4% (44.6-66.4), grade 4 = 20.0% (9.8-40.9); hip: grade 1 = 100.0% (100.0-100.0), grade 2 = 40.4% (26.7-61.3), grade 3 = 14.3% (8.1-25.0), grade 4 = 11.6% (3.6-37.6); and 7 years: knee: grade 1 = 93.3% (81.5-100.0), grade 2 = 71.5% (57.1-89.6), grade 3 = 52.2% (42.1-64.7), grade 4 = 20.0% (9.8-40.9); hip: grade 1 = 100.0% (100.0-100.0), grade 2 = 40.4% (26.7-61.3), grade 3 = 14.3% (8.1-25.0), grade 4 = 11.6% (3.6-37.6).

contrast, our study cohort consists of patients that were referred to the orthopedic department by their GP for consideration of surgery and triaged to the JC. If the 29 patients who were referred for surgery at their initial JC appointment were excluded then 149 on 308 patients (48%) had not progressed to surgery which gives a very similar result to the Australian study where there were no access barriers to surgery.

Like us, Dabare et al [8] found that patients with hip OA (60%) were more likely to have undergone surgery than those with knee OA (33%) at 6 years. They reported that the rate of progression to surgery declines after 3 years for both hip and knee cohorts. Our results show a similar trend with patients with hip OA requiring surgery earlier than knees, but a flattening of the curves after the 3-year mark and roughly equal rates thereafter (Fig. 2). This may be because patients fit enough for surgery will have it early while less medically fit patients will remain. Svege et al [7], in a randomized control trial of 109 patients with hip OA that compared usual care with an exercise program, reported 75% patients progressing to surgery with usual care, compared to 59% in the group provided an exercise therapy program. The slope of the Kaplan-Meier curve in their study did not appear to vary over the 6-year period.

It is not surprising that we found a strong association with K-L grade and progression to surgery. At baseline, 227 of 337 patients (67%) had advanced changes (K-L stage 3 and 4). The odds of a patient with K-L grade 3 progressing to surgery was twice that of a patient with K-L grade 1 or 2 OA, and the odds of patients with K-L grade 4 OA progressing to surgery were 4.79 times those with K-L grade 1 or 2 disease. Patients with knee OA showing K-L grade 4 changes had a rate of progression to surgery that was comparable with stage 3 and 4 hip OA but a better prognosis for other grades. Dabare et al [8] reported very similar HRs for K-L stage 3 (HR 2.62, not significant) and 4 (HR 4.96, $P = .001$) changes compared with grade 1 and 2. Radiographic changes do not always correlate with symptoms; Skou et al [22], in a large series of 1414 patients with knee OA (82% K-L stage 3 and 4) at 1-5 years of follow up, reported that nonoperative treatment improved pain regardless of

Table 2
Relationship Between Baseline Variables and Time-to-Surgery.

Baseline Variable	Univariate Cox Regression	Multivariate Cox Regression
Joint		
Knee	Reference	
Hip	2.63 (1.95-3.53)[a]	2.80 (2.05-3.83)[a]
Age (y)	1.08 (1.00-1.16)[b]	1.03 (0.96-1.11)
Gender		
Male	Reference	
Female	0.87 (0.65-1.16)	0.91 (0.67-1.23)
BMI	0.92 (0.80-1.06)	–
K-L grade		
Grade 1-2	Reference	
Grade 3	2.70 (1.82-3.99)[a]	2.02 (1.33-3.07)[a]
Grade 4	5.43 (3.46-8.51)[a]	4.79 (2.96-7.77)[a]
Health-related quality of life scales		
Oxford Hip/Knee Score	0.74 (0.67-0.82)[a]	0.74 (0.66-0.85)[a]
SF-12 PCS score	0.86 (0.79-0.94)[a]	0.96 (0.86-1.06)
SF-12 MCS score	0.97 (0.91-1.04)	1.08 (1.00-1.16)

All cells report hazard ratio (95% confidence interval). Hazard ratios for continuous variables (age, BMI, health-related quality of life scales) are reported for a 5-point change in the continuous scale. BMI was dropped due to the proportion of missing values.
BMI, body mass index; K-L grade, Kellgren-Lawrence radiographic osteoarthritis grade; SF-12, Short Form 12; PCS, Physical Component Summary; MCS, Mental Component Summary.
[a] $P < .01$.
[b] $P < .05$.

Table 3
Relationship Between Baseline Variables and Time-to-Surgery, Stratified by Affected Joint.

Baseline Variable	Knee	Hip
Age (y)	1.14 (0.97-1.33)	1.01 (0.93-1.10)
Gender		
Male	Reference	
Female	0.69 (0.42-1.11)	0.97 (0.64-1.47)
K-L grade		
Grade 1-2	Reference	
Grade 3	2.52 (1.29-4.95)[a]	1.65 (0.96-2.83)
Grade 4	8.27 (3.91-17.47)[a]	3.14 (1.65-5.98)[a]
Health-related quality of life scales		
Oxford Hip/Knee Score	0.77 (0.58-1.01)	0.74 (0.63-0.86)[a]
SF-12 PCS score	0.79 (0.64-0.98)[b]	1.01 (0.89-1.15)
SF-12 MCS score	0.98 (0.85-1.13)	1.14 (1.03-1.26)[b]

All cells report hazard ratio (95% confidence interval), from a multivariate model including all other covariates. Hazard ratios for continuous variables (age, BMI, health-related quality of life scales) are reported for a 5-point change in the continuous scale.
BMI, body mass index; K-L grade, Kellgren-Lawrence radiographic osteoarthritis grade; SF-12, SF-12, Short Form 12; PCS, Physical Component Summary; MCS, Mental Component Summary.
[a] $P < .01$.
[b] $P < .05$.

radiographic severity. Dowsey et al [23,24] reported poorer outcomes after THA and TKA in patients with less severe radiographic changes, suggesting that caution should be exercised before recommending surgery in patients with less severe radiographic disease.

The baseline OHS or OKS was a significant determinant of progression to surgery with a 34% increase in risk of surgery for each 5 point lower OHS/OKS at baseline. When patients with knee OA were analyzed separately, the baseline OKS had a similar trend but just failed to reach significance due to wide confidence intervals; however, the SF-12 PCS was significantly associated with progression to surgery. This suggests that both condition-specific PROMs such as the OHS/OKS and general scores such as the SF-12 are useful in prioritizing healthcare decisions. These results are consistent with those of Dabare et al [8] in their univariate model; however, in the multivariate model only pain scores remained significant. This difference may be explained by our use of a prioritization tool during the time of this study which has been shown to correlate well with the OHS/OKS [13], whereas the study of Debare et al was in a setting in which there was ready access to surgery and no surgical prioritization was used.

We found no significant association between age and progression to surgery. The relationship with age is complex. A surgeon may be less likely to offer surgery to a younger patient because of the increased risk of requiring a revision procedure or to an older patient because of elevated surgical risk due to comorbidities. An older patient may be less able to participate in an exercise program or may tolerate pain and loss of function less well, but conversely may have lower demands than a younger patient. Dabare et al [8] found that the influence of age followed an inverted U appearance (a quadratic function), with the largest hazard of surgery at 67 years, which may reflect these competing influences.

Dabare et al [8] concluded that a larger proportion of patients with hip OA present with worse symptoms, and require earlier arthroplasty than those with knee OA. However, as the progression to surgery slows down after 3 years there is a major role for conservative treatment of both hip and knee OA patients in the long term. They advocated persistence with conservative treatment regardless of stage of disease at presentation. Those needing surgery will become apparent but a large proportion will not need surgery within 5 years which will have a great effect on the health budget.

In contrast, we found no difference in baseline presentation between patients with hip and knee OA. Our healthcare system has more limited access to surgery, there is explicit rationing and patients need to deteriorate significantly to qualify for publicly funded surgery.

Our experience has been that patients with hip OA progress more rapidly, are more disabled, and therefore more likely to qualify for surgery than patients with knee OA [12,15,16]. There was no improvement with nonoperative treatment in the group with hip OA and a greater proportion had deteriorated than improved by a clinically relevant amount. However, there was a modest improvement in OKS in the group with knee OA still being managed nonoperatively with a greater proportion improving rather than deteriorating. This suggests for patients with knee OA that while nonoperative treatment had limited gains, there was no significant deterioration in the group that had not undergone surgery.

We agree that good nonoperative treatment should be trialed. However, our data suggest that 80% patients with hip OA with KL grades 3 and 4 will deteriorate and require THA within 3-5 years. This should be reflected in surgical prioritization as there is little point in delaying surgery for these patients. A high proportion of patients with knee OA especially with less severe radiographic changes may not require surgery at 5 years with good nonoperative management and we recommend efforts be directed toward this group.

The strength of this study is that it used prospectively gathered data of a large cohort over 5 years. All patients were referred for orthopedic assessment by their GP with an expectation that surgery should be considered. We were able to access patient records and the New Zealand Joint Registry to collect surgical information, and JC appointment details for all patients. Two-thirds had advanced (KL grade 3 or 4) radiographic changes. Therefore we are reporting a real-world situation and believe that this study is generalizable to similar healthcare systems.

The principal limitation of this study is the observational design, from which we cannot distinguish between the effect of the JC and the natural history of the disease. In OA symptoms can fluctuate, though typically slowly deteriorate. We believe that we are reporting the results of good nonoperative treatment through an individualized program [14,16]. We have used the hard end point of arthroplasty surgery, acknowledging however that the intervention rate for THA and TKA varies between countries. The decision to offer surgery is complex and the indications and threshold to offer surgery vary between healthcare systems. We are obliged to prioritize (ration) surgery using prioritization tools. Therefore the low surgical rate may be in part due to access barriers resulting in patients having to accept their pain and disability. Although only 9 patients were advised surgery but failed to qualify due to the financial threshold, it is possible that other patients had learned to live with their problem and did not request re-referral, or were not referred back for surgery by their GP, because of the known capacity constraints. This may be true for those with hip OA as there was no improvement and a greater proportion had deteriorated than improved by a clinically relevant amount. However for the group with knee OA that had not undergone surgery, there was a modest improvement in OKS with a greater proportion improving rather than deteriorating. It was beyond the scope of this study to do a full cost-effectiveness analysis. However, we have previously reported that the marginal cost of delivering the JC was NZ$550 (year 1) and NZ$384 (year 2) per patient [14]. This compares with an average cost to the DHB of approximately NZ$16,000 for a THA or TKA. By delaying or avoiding surgery in even a small proportion of patients for 5 years, it has proven to be both an economic and clinical success.

The results of this study have shown that nonoperative treatment may delay or even prevent the need for surgery at 5-7 years in more than 50% of patients with knee OA, especially in those with K-L stage 3 or less. Patients with hip OA, especially with more severe radiographic changes and those with K-L grade 4 knee OA, are significantly more likely to require surgery and should not be delayed if there is not an adequate response to conservative measures. Poorer patient-reported scores were also predictive of the need for surgery and should be considered as part of the prioritization process.

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Joint Preservation

The Functional Outcomes of Patients With Knee Osteoarthritis Managed Nonoperatively at the Joint Clinic at 5-Year Follow-Up: Does Surgical Avoidance Mean Success?

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ABSTRACT

Background: Nonoperative management of patients with knee osteoarthritis (OA) through multidisciplinary programs may delay or reduce the need for total knee arthroplasty (TKA). However, avoidance of surgery may not represent success for the patient.
Methods: A cohort of 120 patients with knee OA managed with at least 6 months of supervised nonoperative treatment coordinated through the Joint Clinic were reviewed at 5 years. Outcomes including Oxford knee score (OKS), Short Form 12 (SF-12), and SF-6D and other measures including analgesia use, global change, and perception of need for surgery were collected and compared with those from the cohort who had undergone TKA.
Results: Seventy (62.5%) surviving patients were still being managed nonoperatively. There was no significant change in any outcome score (OKS, SF-12 physical component score, SF-12 mental component score, SF-6D) ($P = .26$ to $.84$). Forty-two patients had undergone TKA with mean time to surgery 29.0 months (range, 9-69 months). In this group, the mean OKS fell from 17.9 at baseline to 10.3 (range, 3-21) preoperatively ($P < .0001$) and at 5 years there was a significant improvement from baseline in OKS, SF-12 physical component score, and SF-6D scores ($P < .0001$). All outcome scores and change in scores were significantly higher for the surgical group (all $P < .001$).
Conclusion: Although a high proportion of patients with knee OA have avoided surgery at 5 years, their outcomes show no improvement from baseline and are poorer than those who have undergone TKA. Avoidance of surgery should not necessarily be regarded as an indicator of success of nonoperative treatment for the patient.

There is a rapidly increasing demand for total knee arthroplasty (TKA) which is challenging publicly funded health services [1–4]. There has been much debate about the appropriate level of symptoms for surgery with large variations between different healthcare systems [5,6]. Increasingly, in New Zealand (NZ) and elsewhere, there is a need for rationing of procedures such as TKA [7,8]. Surgery at the right time is highly effective with case series and registry reports showing large improvements in pain and function and excellent long-term revision-free survival. However, up to 20% of patients may be dissatisfied with the results of TKA and complications of surgery may be severe [9,10]. In this environment, it is important that nonoperative treatment of patients is optimal.

Nonoperative management of patients with knee osteoarthritis (OA) through an individualized multidisciplinary program is recommended in American College of Rheumatology, European League against Rheumatism, Osteoarthritis Research Society International, and National Institute of Clinical Excellence guidelines [11–14]. It has been shown to be effective and may delay or even avoid the need for TKA [15–17].

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We developed the Joint Clinic (JC), a physiotherapist and nurse–led clinic to improve access for patients with hip and knee OA. Patients referred to the orthopedic department for consideration of surgery and triaged to the clinic receive an individualized nonoperative management program [18]. The JC has been shown to be an effective triage tool [19]. Patients with knee OA and those with milder symptoms were more likely to respond to nonoperative treatment than those with hip OA and we recommended that nonoperative management was best directed toward these patients [19,20]. This was confirmed in our 5-year results where over 50% of patients with knee OA were still being managed nonoperatively at 5- to 7-year follow-up. Patients with hip OA, more advanced Kellgren-Lawrence (K-L) grade, and worse Oxford hip/knee score (OHS/OKS) were predictive of the likelihood of undergoing surgery [17]. However, while surgical avoidance may be seen as a safe and desirable outcome for patients and overstretched health services, it may not represent treatment success to the patient. There are little data on the outcomes of patients treated nonoperatively at long-term follow-up and how they compare with patients who have undergone surgery.

The aim of this study is to report the patient-reported functional outcomes of patients with knee OA managed nonoperatively through the JC at 5-year follow-up after their initial assessment. The secondary aim is to compare those patients who underwent surgery after their initial period of nonoperative treatment with those who have continued with nonoperative treatment.

Patients and Methods

The JC was set up to improve access and nonoperative management for patients referred to the orthopedic department of our Public Hospital with hip and knee OA. Patients were triaged to the clinic by a consultant orthopedic surgeon and assessed by an experienced physiotherapist and orthopedic nurse. An individualized management program was developed which included advice on their condition, optimization of analgesia, and referral for an outpatient physiotherapy OA program, occupational therapy, dietician advice, or orthotic management where indicated [18]. Patients were reviewed every 6 months until they were discharged back to general practitioner if their symptoms were stable, or they had deteriorated to the extent that they needed referral for surgical assessment. Radiological assessment was only repeated as needed.

In New Zealand, patients only qualify for publicly funded surgery if there is capacity for the procedure to be done within 4 months. If a surgeon recommends surgery, the patient is scored using a prioritization tool [8]. If the patient scores below the threshold score, they are declined surgery and returned to the care of their general practitioner for nonoperative management. However, there is the option for clinical override in special cases.

This is a prospective observational cohort study comprising 120 patients with knee OA who were assessed in the JC between June 2012 and May 2014 and were treated with a minimum 6-month trial of individualized nonoperative treatment. Inclusion criteria for the initial study were all patients seen and subsequently reviewed at JC with a diagnosis of knee OA (unilateral or bilateral). Exclusions were patients referred for surgical assessment at their initial JC appointment, self-discharge, or failure to attend a follow-up appointment at 6 months. We have previously reported the outcomes of this cohort at 12-month follow-up [20]. By the time of this review at 5 years, 8 patients (7%) had died without surgery, 70 (58%) were still being managed nonoperatively, and 42 patients (35%) had undergone TKA with the mean time to surgery from initial assessment 29.0 months (range, 9-69 months).

Patient-reported outcome measures (PROMs) including OKS [21] and Short Form 12 (SF-12) [22] were collected at the initial JC appointment and subsequent appointments. All baseline radiographs were assessed and graded according to the K-L classification by 2 observers [23]. A questionnaire was sent out to all surviving patients including the OKS and SF-12. This allowed calculation of OKS, SF-12 physical and mental component scores (PCS, MCS), and SF-6D utility [24]. The 5-year OKS was also categorized according to the classification of Kalairajah et al [25]. The minimum important difference (MID) in OKS was taken as 5 points as used in our previous article [20,26]. There were further questions including their use of walking aids, analgesia, and use of physical therapy exercises. They were also asked to indicate their global change from baseline using a global impact of change question and their satisfaction with JC. Patients who had not undergone surgery were asked how they currently rated their need for surgery. Surgical patients were asked about any complications and a full chart review performed of all surgical patients for any adverse effects. The preoperative OKS was also collected in these patients. The NZ Joint Registry (NZJR) was used to check whether any patients had undergone either primary or revision surgery elsewhere [27].

Statistical analysis was performed using R version 3.6.0 (R Core Team) [28]. Chi-squared tests were used for categorical variables and *t*-test for continuous variables. Statistical significance was taken as $P < .05$.

Ethics approval was given by the University of Otago Ethics Committee (Health). All patients gave written consent to be included in the study.

Table 1
Baseline Characteristics of the Study Cohort and the Nonoperative and Surgical Groups.

Baseline Characteristic	All Patients	Nonoperative	Surgery	Difference Between Groups *P* Value
Total, n	120	78	42	
Age (y)	68.7 (9.0)	67.8 (9.8)	70.3 (7.1)	.15
Gender				.58
Male	53 (44%)	33 (42%)	20 (48%)	
Female	67 (56%)	45 (58%)	22 (52%)	
BMI (kg/m^2)	31.0 (5.6)	31.0 (6.3)	31.0 (4.6)	.99
K-L grade				<.0001
Grade 1	10 (8%)	10 (13%)	0 (0%)	
Grade 2	32 (27%)	26 (33%)	6 (14%)	
Grade 3	59 (49%)	37 (47%)	22 (52%)	
Grade 4	19 (16%)	5 (6%)	14 (33%)	
OKS	20.3 (7.3)	22.1 (7.6)	17.1 (5.4)	.0003
SF-12 PCS	32.1 (8.3)	33.2 (8.9)	29.9 (6.5)	.04
SF-12 MCS	49.2 (12.3)	50.3 (12.4)	46.9 (12.0)	.16
SF-6D utility	0.61 (0.12)	0.63 (0.13)	0.57 (0.09)	.03

BMI, body mass index; K-L, Kellgren-Lawrence grade; OKS, Oxford knee score; SF-12 PCS, Short Form 12 physical component score; MCS, mental component score.
Values are given as mean (standard deviation) or number (%).

Results

The mean follow-up period was 5.5 years (range, 4.5-6.5 years). Of 112 surviving patients, 77 (69%) responded to the questionnaire with no difference in proportion responding between surgical (28 of 42, 67%) and nonoperative groups (49 of 70, 70%) ($P = .87$). There was no significant difference between respondents and nonrespondents with respect to gender, K-L grade, or baseline OKS, SF-12 PCS, or SF-6D utility scores. However, respondents were younger ($P = .040$) and had lower baseline body mass index (BMI) ($P = .048$) and higher SF-12 MCS scores ($P = .010$) than nonrespondents (Table S1). The nonoperative and surgical groups at baseline were similar with respect to age, gender, BMI, and SF-12 MCS (Table 1). The OKS, SF-12 PCS, and SF-6D utility were lower and the K-L grade was more advanced in the surgical group at baseline.

Table 2
Patient-Reported Outcome Scores for Respondents at Baseline and 5 Years.

Outcome Score	Nonoperative			Surgery		
	5-y Follow-Up	Change From Baseline	*P* Value	5-y Follow-Up	Change From Baseline	*P* Value
OKS	23.3 (8 to 48)	1.2 (−24 to 22)	.38	38.4 (20 to 48)	19.6 (5 to 36)	<.0001
SF-12 PCS	30.7 (14.0 to 56.7)	−1.9 (−26.0 to 24.1)	.26	46.1 (17.7 to 60.8)	15.6 (−29.9 to 37.9)	<.0001
SF-12 MCS	51.5 (20.1 to 68.5)	−1.0 (−28.0 to 35.8)	.60	51.2 (12.5 to 64.0)	2.8 (−33.9 to 25.4)	.32
SF-6D utility	0.633 (0.345 to 0.922)	−0.006 (−0.544 to 0.371)	.84	0.787 (0.567 to 1.000)	0.201 (0.032 to 0.416)	<.0001

The values are given as mean (range).
The 5-y scores for the surgical group were significantly higher than the nonoperative group for all scores and change in scores ($P < .001$) with the exception of MCS ($P = .76$) and change in MCS ($P = .24$).
OKS, Oxford knee score; SF-12 PCS, Short Form 12 physical component score; MCS, mental component score.

Of the 49 respondents still being managed nonoperatively, 18 (36%) patients had improved and14 (28%) deteriorated by OKS $\geq$ 5 points. Of all 77 respondents (surgery and nonoperative), 42 (55%) had deteriorated by OKS $\geq$ 5 points or had undergone surgery and only 18 (23%) had improved by OKS $\geq$ 5 points with nonoperative treatment at 5 years. In patients still being managed nonoperatively, there was no statistically significant change in any of the 4 outcome scores (OKS, SF-12 PCS, SF-12 MCS, and SF-6D) at 5 years compared with baseline (*P* value range, .26-.84) (Table 2).

At 5-year follow-up, 10 (20%) of the nonoperative group rated themselves as very much or quite a lot better and 27 (55%) as quite a lot or very much worse. Thirty-two (65%) patients were taking pain relief daily or on most days, and 19 (39%) were using walking aids (stick, frame crutches) (Table 3). Most patients reported their experience of JC to be good or excellent (33, 67%). Almost half (24 of 49, 49%) were still performing regular physical therapy exercises.

Five patients (10%) indicated that they either were on a wait-list or wanted surgery but did not qualify due to the prioritization process. All showed clinically meaningful deterioration on all or most outcome scores. A further 13 patients (27%) were getting to the stage of wanting something done. Their mean scores had deteriorated by a clinically significant margin, although there was wide variability and some patients showed significant improvements. Six patients (12%) said they did not need or want surgery. Their PROMs were the highest and all showed improvements in OKS and most other scores. The largest group of patients (24, 49%) had learned to live with the problem. Their mean scores were intermediate with improvements in OKS, MCS, and SF-6D although the range was wide. The patient perception of their requirement for surgery (ie, increasing dissatisfaction with nonoperative treatment) was associated with a decrease in all PROMs (Table 4).

Of the 42 patients who had undergone TKA, there were 5 patients (12%) with adverse events related to their surgical procedure. One patient had anaphylaxis on anesthetic induction and the procedure was abandoned. She subsequently had an uneventful TKA. There were 3 thromboembolic complications: 2 patients developed small soleal sinus deep vein thromboses and one a small right upper lobe segmental pulmonary embolus, all of which resolved with treatment. A 71-year-old man developed an acute kidney injury requiring dialysis and a subsequent hematemesis but made a complete recovery. At mean 3.9-year follow-up (0.8-6.0 years) postsurgery, there have been no revisions or reoperations and none of the surgical group had died.

The mean OKS in the surgery group had fallen from 17.9 at baseline to 10.3 preoperatively ($P < .0001$) (Fig. 1). At 5 years, there were statistically significant improvements from baseline on OKS

Table 3
Use of Walking Aids, Pain Medication at Baseline and Final Review, and Global Change From Baseline for Nonoperative and Surgical Respondents at 5 Years.

Patient Response	Baseline		Final Review		Difference Between Groups at Final Review *P* Value
	Nonoperative	Surgery	Nonoperative	Surgery	
Walking aids					
None	36 (72%)	16 (57%)	25 (51%)	16 (57%)	.67
1 crutch	1 (2%)	5 (18%)	2 (4%)	2 (7%)	
2 crutches	0 (0%)	0 (0%)	1 (2%)	0 (0%)	
Stick	10 (20%)	7 (25%)	13 (27%)	6 (21%)	
Stick +2 crutches	0 (0%)	0 (0%)	0 (0%)	2 (7%)	
Frame	2 (4%)	0 (0%)	1 (2%)	1 (4%)	
Frame + stick/crutches	0 (0%)	0 (0)%	2 (4%)	1 (4%)	
Did not answer			5 (10%)	0 (0%)	
Pain medications					
Rarely/never	11 (22%)	2 (7%)	7 (14%)	11 (39%)	.02
Occasionally	4 (8%)	3 (11%)	9 (18%)	5 (18%)	
Once or twice a week	7 (14%)	0 (0)%	1 (2%)	2 (7%)	
Most days	8 (16%)	3 (11%)	7 (14%)	4 (14%)	
Daily	19 (39%)	20 (71%)	25 (51%)	5 (18%)	
Did not answer			0 (0%)	1 (4%)	
Change from baseline					
Very much better			6 (12%)	17 (61%)	<.0001
Quite a bit better			4 (8%)	4 (14%)	
Slightly better			3 (6%)	2 (7%)	
Not changed			3 (6%)	3 (11%)	
Slightly worse			5 (10%)	0 (0%)	
Quite a bit worse			20 (41%)	0 (0%)	
Very much worse			7 (14%)	1 (4%)	
Did not answer			1 (2%)	1 (4%)	

Values are given as number (%).

Table 4
Patient-Reported Perception of Need for Surgery and Scores of Patients Still Managed Nonoperatively.

Patient Reponse	N (%)	OKS		SF-12 PCS		SF-12 MCS		SF-6D Utility	
		5-y Follow-Up	Change From Baseline	5-y Follow-Up	Change From Baseline	5-y Follow-Up	Change From Baseline	5-y Follow-Up	Change From Baseline
Do not need/want surgery	6 (12%)	35.8 (27 to 48)	12.0 (1 to 22)	41.1 (22 to 57)	9.7 (−7 to 24)	60.9 (52 to 68)	4.6 (−9 to 18)	0.83 (0.74 to 1.00)	0.17 (0.00 to 0.27)
Learned to live with it	24 (49%)	24.6 (14 to 40)	4.3 (−9 to 21)	32.2 (17 to 53)	−0.2 (−19 to 14)	51.6 (20 to 69)	3.3 (−17 to 36)	0.65 (0.34 to 0.92)	0.07 (−0.24 to 0.37)
Getting to stage of wanting something done	13 (27%)	19.2 (8 to 32)	−5.2 (−24 to 7)	26.3 (19 to 33)	−8.3 (−26 to 9)	45.7 (20 to 67)	−8.1 (−28 to 9)	0.55 (0.34 to 0.70)	−0.14 (−0.54 to 0.06)
Would like/have been advised surgery but cannot get in	3 (6%)	14.7 (8 to 19)	−8.3 (−9 to −8)	23.1 (14 to 30)	−6.2 (−9 to −5)	48.6 (42 to 58)	−11.6 (−17 to −2)	0.53 (0.49 to 0.55)	−0.15 (−0.20 to −0.11)
Wait-listed for surgery	2 (4%)	13.0 (10 to 16)	−8.5 (−12 to −5)	18.7 (15 to 23)	−13.9 (−18 to −10)	54.7 (48 to 61)	−9.1 (−16 to −2)	0.54 (0.53 to 0.54)	−0.24 (−0.32 to −0.16)
Did not answer	1 (2%)	27	5	31.7	−0.2	54.2	−2.2	0.63	0.06

The values are given as mean (range).
OKS, Oxford knee score; SF-12 PCS, Short Form 12 physical component score; MCS, mental component score.

(+19.6), SF-12 PCS (+15.6), and SF-6D utility (+0.201) (all $P <$ .0001), and no significant change in MCS scores ($P = .32$) (Table 2). Nineteen patients (73%) had good or excellent OKS scores (≥34). Four patients (15%) in the surgery group had an OKS <27 (poor). All had improvements in OKS of 5 to 8 points and reported an improvement from baseline. Twenty-one (75%) rated themselves as very much or quite a lot better, while 1 (4%) rated themselves as quite a lot or very much worse (Table 3). He had a good early result after TKA but developed loosening of an ipsilateral total hip arthroplasty which is thought to be a significant contributor to his symptoms. Most patients in the surgery group were taking pain medication rarely (11, 39%) or occasionally (5, 18%), and 12 (43%) were using walking aids (Table 3). Most reported their JC experience to be good or excellent (20, 71%), and all respondents had improved by ≥5 points on OKS. Half were still performing regular physical therapy exercises.

All outcome scores and change in scores from baseline were significantly higher for the surgical group than the nonoperative group ($P <$ .001) (Table 2, Fig. 1). Patients in the surgical group were less likely to take pain relief regularly ($P = .02$) and a significantly higher proportion of patients rated themselves as very much or quite a bit better after surgery ($P <$ .0001). There were a significantly higher proportion of patients with a good and excellent OKS in the surgical group (76% vs 18%) and a lower proportion with a poor OKS (12% vs 69%) (chi-squared, $P <$ .001) (Table 5).

There was no significant difference in the use of walking aids, the proportion still performing regular physical therapy exercises, and the satisfaction with their experience of JC between the surgery and nonoperative groups.

Discussion

This study has shown that 62.5% of surviving patients with knee OA seen at the JC were still being managed nonoperatively at 5-year follow-up with no significant change from baseline in any patient-reported outcome measures (OKS, SF-12, SF-6D). Also, 23% of respondents had improved by a clinically relevant amount while 55% had deteriorated or undergone surgery. The nonoperative group had statistically significant and clinically relevant poorer outcomes at 5 years than those patients who had undergone TKA. In the surgical group, there were few adverse effects of surgery and no reoperations.

The patients seen at JC represent those at the milder end of the spectrum that we are referred. Patients in this cohort were all referred for consideration of surgery but were felt at initial assessment to be below the threshold to qualify for surgery. They had a minimum of 6 months of supervised nonoperative treatment. In our previous study of this cohort at mean 1-year follow-up, 35% patients with knee OA improved by ≥5 points on OKS while 21% had deteriorated by ≥5 points. In total, 29 patients (24%) had undergone TKA [20]. At 5 years, the number who had undergone TKA had risen to 42 (35%). Many of the patients still being managed nonoperatively had not had any clinically relevant deterioration over 5 years despite the usual progressive nature of OA. However, the results of nonoperative treatment for the group as a whole showed a decrease in OKS, if the preoperative scores of the surgical group who failed nonoperative management are included.

Similar clinics have been developed in other centers which show that gains can be made even in patients referred with advanced disease [15,16,29,30]. Skou et al in a randomized, controlled trial of patients eligible for TKA showed that 68% of the nonoperative group had avoided surgery at 2 years [16]. This has been used to promote large-scale programs such as Good Life with osteoarthritis in Denmark (GLA:D[)]) which has been introduced to other countries including Canada and Australia [31]. It is hoped that these programs

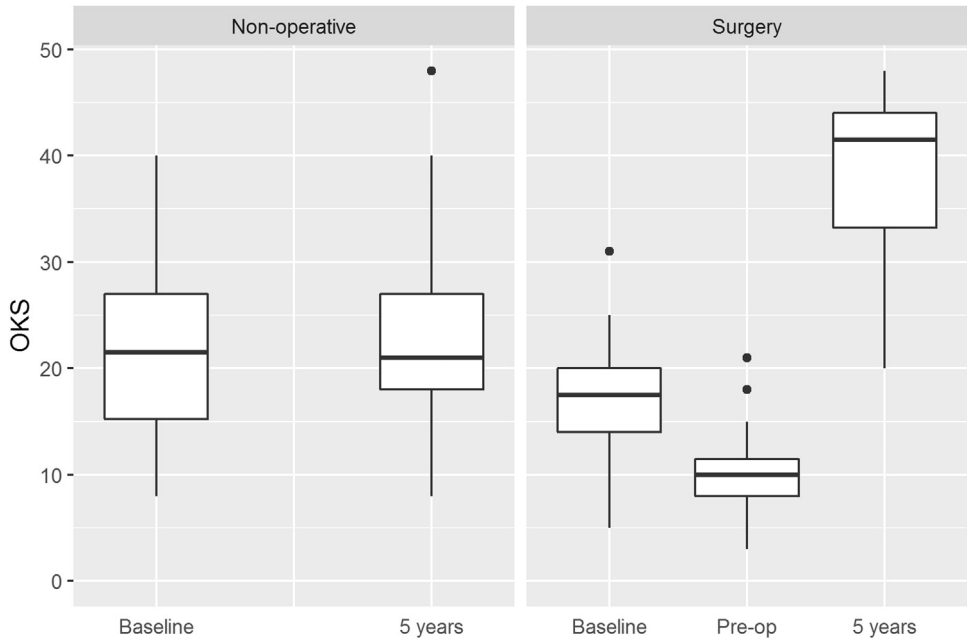

Fig. 1. Box and whisker plot showing changes in Oxford knee score (OKS) from baseline for nonoperative and surgical groups.

may reduce the demand for TKA. However, at this stage, the results are only to 2 years and it is not clear whether the need for TKA is merely being delayed [16].

We have previously reported that surgery can be avoided in 56% of patients with knee OA and 24% of those with hip OA at 5 years in our healthcare setting where there is explicit rationing of surgery [17]. In this cohort, where we included only those that were compliant with treatment for at least 6 months, 76% had avoided surgery at 1 year and 65% at 5 years. Similarly, Dabare et al [15] using a multidisciplinary clinic with ready access to surgery when required showed that 67% of patients with knee OA and 40% of patients with hip OA had avoided surgery at 6 years. However, few details were reported in their study on the status of these patients who had "successful" nonoperative management with 77% of patients giving "an improvement with conservative treatment" as the reason for not having surgery.

In our study, there were clinically relevant improvements in scores in the small group (12%) of patients who felt they did not need or want surgery. There were also smaller improvements seen in the larger group of respondents (49%) who had learned to live with the problem. The group (27%) that were "getting to the stage of wanting something done" had an average deterioration on all outcomes but had a wide range of scores with some improving and others deteriorating by clinically relevant amounts. Only 5 patients (10% of respondents) have been advised or wait-listed for surgery but have not qualified. Their scores were poor and showed deterioration from baseline on all scores. All patients were initially referred for consideration of surgery and many of these patients may have undergone surgery elsewhere or if there was better access to surgery in our institution. The JC has been very successful at reducing the surgical burden but this study suggests that this reduction is not so much due to the success of nonoperative management but rather our environment has altered the expectation of patients regarding surgery.

Table 5
Number of Patients by OKS Category at 5 Years (Kalairajah et al [25]).

Category	OKS	Nonoperative	Surgery
Poor	<27	31 (69%)	3 (12%)
Fair	27-33	6 (13%)	3 (12%)
Good	34-41	7 (16%)	6 (24%)
Excellent	42-48	1 (2%)	13 (52%)

Chi-squared 31.5, $P < .0001$.
Values are given as number (%).
OKS, Oxford knee score.

It is well known that TKA is a highly effective intervention for end-stage OA. However, the literature suggests that 15%-20% of patients may be dissatisfied with TKA and complications of surgery may be serious [9,10]. In a randomized, controlled trial comparing nonsurgical treatment alone with TKA and nonsurgical treatment, there was improved pain relief and functional outcomes in the TKA group at 2 years but an increased risk of serious adverse events [16,32]. They reported 24 serious adverse events in 50 patients who underwent TKA with 8 involving the index knee: 3 knees requiring manipulation under anesthesia, 1 deep infection, 1 supracondylar fracture femur, and 3 deep vein thromboses [32]. In contrast, we saw only 5 complications in 42 patients (12%) with no knees requiring manipulation under anesthesia and no subsequent revision procedures or reoperations at a mean follow-up of 3.2 years. While surgery is a major intervention with risks, with modern techniques including enhanced recovery programs these can be minimized [33].

In this study, the postoperative mean OKS of 38.4 in those who underwent TKA compares favorably with the NZJR (OKS 37.7 at 6 months), despite the low mean preoperative OKS [27]. In the surgical group, only 3 patients (12%) had a poor result with OKS <27 but all had a gain of OKS of 6-8 points and reported an improvement from baseline. In contrast, 69% of those managed nonoperatively had a poor result using the same OKS criteria.

We have compared outcomes of patients treated surgically and those who continued with nonoperative treatment from a cohort where the intention was to treat nonoperatively. The baseline characteristics of patients in these groups were reasonably well matched with respect to age, gender, and BMI but patients who underwent surgery had poorer PROMs and radiographic changes at

baseline. Despite this, all outcome scores and change in scores were significantly higher for the surgical group compared to those still being managed nonoperatively and at or above the MID reported for all scores [26,34,35]. Health-related quality of life (HRQoL) as measured by the SF-6D showed a gain of 0.201 with surgery which is well above the MID of 0.041 [35]. The difference in SF-6D between the surgical and nonoperative groups of 0.129 at 5 years gives an indication of the potential loss of quality-adjusted life years for patients continuing with nonoperative treatment rather than having a TKA.

A significant limitation is our response rate. It is particularly difficult to follow up patients who have not had a surgical procedure and may not even remember their JC appointment 5 years earlier. Most patients are elderly and we had more success with paper-based than web-based questionnaires while telephone surveys were of limited value. There may be recall bias in the responses to the more subjective questions especially regarding their perception of global change from baseline. However, the patient-reported scores, which were our primary outcome measure, were collected prospectively. A further limitation is that this study is observational. We are likely to be reporting the natural history of knee OA in patients who have had good nonoperative management rather than the results of a specific intervention. The study focusses on functional outcomes and radiological review was not included in the protocol. Radiographs were only repeated as necessary such as preoperatively for the surgical group so many in the nonoperative group did not have radiographs at final review. It is possible that booster doses of nonoperative treatment including physiotherapy may have improved the results. However, equal proportions of those that improved had either continued or stopped physiotherapy, suggesting that this is unlikely to have a major bearing.

There were no standardized criteria for surgery in our study and not all patients may have wanted, needed, or been suitable candidates for surgery. Although thresholds for surgery vary across health systems, there is likely to be little debate about the need for surgery in suitable patients with a mean preoperative OKS of 10.3. However, it likely those patients with a higher OKS would be considered for TKA in many other healthcare systems. In the United Kingdom, Dakin et al [36] suggested that, based on HRQoL gains, the most cost-effective preoperative OKS was 12-15 points but TKA remained cost-effective even in patients with an OKS up to 35-40 points. In the United States, Ferket et al [37] suggested that TKA would be more effective if restricted to patients with SF-12 PCS <50 and was most attractive from an economic viewpoint in patients with a score <35 points. However, we do not believe that scores such as OKS or PCS should be used to determine access to TKA alone. The decision to offer surgery is complex and should involve clinical and radiological assessment of the patient by an orthopedic surgeon.

Strengths of this study are the detailed outcomes including patient-reported scores and length of follow-up for a nonoperative cohort. We are confident that we have identified all those who have undergone TKA and any surgical complications through our electronic records, audit database, and cross-referencing to the NZJR.

Conclusions

Good nonoperative management coordinated through a dedicated JC has resulted in a high proportion of patients with knee OA avoiding surgery at 5 years. However, many have learned to live with their problem and showed little to no improvement in patient-reported outcomes. Their outcomes were poorer than those in the cohort who have undergone TKA. Patients who underwent TKA had low complication rates and significant improvements in HRQoL. When reporting the results of nonoperative management, avoidance of surgery alone should not be regarded as an indicator of success for the patient. TKA should not be withheld or delayed in suitable patients.

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Appendix

Table S1
Baseline Characteristics of Respondents and Nonrespondents to 5-Year Questionnaire.

Baseline Characteristic	All Patients	Respondents	Nonrespondents	Difference Between Groups *P* Value
Total, n	120	77	43	
Age (y)	68.7 (9.0)	69.2 (7.9)	67.8 (10.7)	.43
Gender				.45
Male	53 (44%)	36 (47%)	17 (40%)	
Female	67 (56%)	41 (53%)	26 (60%)	
BMI (kg/m^2)	31.0 (5.6)	30.3 (5.1)	32.9 (6.6)	.05
K-L grade				.71
Grade 1	10 (8%)	5 (6%)	5 (12%)	
Grade 2	32 (27%)	23 (30%)	9 (21%)	
Grade 3	59 (49%)	38 (49%)	21 (49%)	
Grade 4	19 (16%)	11 (14%)	8 (19%)	
OKS	20.3 (7.3)	20.6 (6.9)	19.9 (8.0)	.63
SF-12 PCS	32.1 (8.3)	31.5 (8.3)	33.1 (8.4)	.32
SF-12 MCS	49.2 (12.3)	51.1 (12.8)	45.5 (10.5)	.02
SF-6D utility	0.61 (0.12)	0.62 (0.13)	0.59 (0.11)	.29
Subsequent TKA	42 (35%)	28 (36%)	14 (33%)	.68

BMI, body mass index; K-L, Kellgren-Lawrence radiographic stage; OKS, Oxford knee score; SF-12 PCS, Short Form 12 physical component summary, MCS, mental component summary; TKA, total knee arthroplasty.
Values are given as mean (standard deviation).

FOOT & ANKLE INTERNATIONAL

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Epidemiology and Outcomes of Acute Achilles Tendon Rupture with Operative or Nonoperative Treatment Using an Identical Functional Bracing Protocol

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ABSTRACT

Background: **This study reports on the demographics of acute Achilles tendon rupture in our region and compares the results of a selective approach to operative and nonoperative treatment using an identical rehabilitation program with functional bracing.** ***Materials and Methods:*** **A consecutive series of 363 patients, aged 15 to 60 years, treated over 8.5 years by either open operative repair (143) or nonoperatively (220) were compared with respect to demographics, re-rupture rate, and major wound complication.** ***Results:*** **There was an almost equal number of males (159) and females (152) up to age 50 years but males comprised 73% of patients aged 51 to 60 years. Netball was the most common cause of injury and explains the relatively high incidence in females. In the 143 patients treated surgically there were two re-ruptures (1.4%) and two reoperations for wound complications (1.4%). In the 220 patients treated nonoperatively there were 19 re-ruptures (8.6%), 13 of 113 males (11.5%) and six of 107 females (5.6%). There was a significantly lower re-rupture rate, and reoperation rate in the surgical group ($p < 0.05$). In the nonoperative group there was a significantly lower rate of re-rupture in patients over 40 (six of 119) (4.1%) compared with those 40 years and under (13 of 99, 13.1%) and between females over 40 when compared with males 40 years and under.** ***Conclusion:*** **In our region there is a high incidence of Achilles tendon rupture among women due to netball and results in a younger age of injury than previously reported. Our results support surgery in patients less than 40 years, particularly males, if there are no contraindications. Functional bracing as part of nonoperative treatment can result in low re-rupture rates in patients over 40, especially in females.**

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Level of Evidence: III, Retrospective Comparative Study

Key Words: Achilles Tendon; Rupture; Functional Rehabilitation; Operative Repair

INTRODUCTION

Achilles tendon rupture is a relatively common injury in the adult population and its incidence appears to be increasing.[16,21,22] It is three to four times more common in males.[10,25] The incidence rises rapidly after 25 years of age with a peak around 42 years.[10,21] Females sustaining the injury tend to be 2 to 3 years older than males.[10,16,21] Despite several meta-analyses[1,14] and randomized controlled trials (RCT)[3,18,20] the treatment remains controversial. Operative treatment is generally accepted as having a lower re-rupture rate but a higher rate of wound complications which may be devastating.[1,14,31] Variables in the rehabilitation phase such as duration of casting and weightbearing status make it difficult to compare treatments. Recent trends in management have focused on early motion and functional treatment both after surgery and with nonsurgical management.[5,27,29] This may improve the functional outcome in surgically treated patients[5,13,19,26] and reduce re-rupture rates in patients treated nonoperatively.[11,29]

In 1999 we developed a standardized program for all patients with an Achilles tendon rupture based on the literature available at the time (Table 1). Functional bracing commenced at 4 weeks post-injury whether the patient had been treated surgically or nonoperatively. This study reports on the demographics of acute Achilles tendon rupture in our region and compares the results of a selective approach to operative and nonoperative treatment using an identical rehabilitation program with functional bracing from 4 weeks after injury.

PATIENTS AND METHODS

This study reports on 363 consecutive patients treated for acute traumatic closed rupture of the Achilles tendon over 8.5

Table 1: The Rehabilitation Protocol Used by our Physiotherapy Department Following Surgical Repair or Nonoperative Treatment

0–4 weeks	• Relaxed equinus cast, nonweightbearing
Phase one **4–8 weeks**	• Active only range of motion with knee bent and straight • Gait re-education in CAM walker increase from partial to full weightbearing • Isometric calf exercises • Introduce pool • Manual therapy
Phase Two **8–10 weeks**	• Light Concentric • Passive stretches / lying / sitting • Bilateral calf raises
10–12 weeks	nonweightbearing (ie: sitting) • Cycling with heel flat. • Heavy concentric –bilateral calf raise. • Light eccentric • Proprioception
Phase Three **12–16 weeks**	• Single leg raises. • Progress concentric/eccentric • Jogging • Progress cycling and proprioception
Phase four **4–6 months**	• Progress speed, distance of activity • Running • Plyometrics

years between July 1999 and February 2008 following introduction of the rehabilitation program. Patients were identified from our emergency department database, in patient coding, surgical audit system, and physiotherapy department records. Case note review was performed to confirm the diagnosis of complete rupture and identify complications. Inclusion criteria were a complete, traumatic closed rupture of the Achilles tendon in skeletally mature patients aged 60 years and younger. Patients were excluded if they lived out of our region as we had no control over their subsequent rehabilitation. Chronic ruptures, partial ruptures, tendinosis, and gastrocnemius tears were also excluded. Treatment was individualized based on patient factors including age, activity level and co-morbidities, and surgeon preference. Relative contraindications to surgery were diabetes, tobacco or steroid use or peripheral vascular disease. A younger, high-demand patient or delayed presentation over 24 hours was a relative indication for surgery. We believe that delayed presentation may lead to more retraction of the tendon ends and predispose to re-rupture. If there was a large gap on clinical examination despite full equinus, we usually operated. Ultrasound or MRI was not routinely used to assess gap size. Our department has eight consultant orthopaedic surgeons who have a range of preference from those who treat most patients nonoperatively to those who favor surgery in most cases

Rehabilitation in patients treated operatively or nonoperatively was under the supervision of a physiotherapist either at our institution, at peripheral clinics or by community physiotherapists. The guidelines were circulated to these physiotherapists though no formal education occurred.

Surgery was performed under general or spinal anaesthesia with the patient prone with a single perioperative dose of antibiotic. Tourniquets or self retaining retractors were not routinely used. A short posteromedial incision was made over the defect. A Kessler type two strand absorbable No. 1 core suture was usually used. Multiple interrupted 3/0 absorbable sutures were used to braid the periphery together. Some surgeons preferred to only use 3/0 absorbable peripheral sutures. The paratenon was carefully closed with an absorbable suture and skin closed either with interrupted nylon skin sutures or a subcuticular absorbable suture. The foot was then placed in a relaxed equinus cast for 2 weeks when sutures were removed and the wound checked. A fibreglass cast was then applied in relaxed equinus and removed at 4 weeks post-surgery.

Patients in the nonoperative group were placed in a below-knee cast with the hindfoot in full gravity assisted equinus. The patients in both groups were kept nonweightbearing in a cast.

In both groups the cast was removed at 4 weeks and the affected leg placed in a CAM walker (Tukwila, WA) locked at 20 degrees equinus and worn day and night. Physiotherapy treatment then commenced with the equinus progressively decreased to neutral by 6 to 8 weeks following injury dependent on patient progression. Weightbearing progressed from partial to full as patient tolerance and range of motion allowed. This was usually once the equinus was reduced to 10 degrees or less. The orthosis was removed by 8 weeks. Progression through the program was determined by the physiotherapist in discussion with the surgeon, if required. Clinical assessment was performed by the orthopaedic surgeon at 8 weeks to assess tendon continuity. No imaging studies were routinely performed. Phase two from 8 to 12 weeks included active and passive stretches, concentric and eccentric muscle strengthening and proprioception. Aquajogging, increasing weightbearing, and cycling with heel flat was allowed.

After 3 months, gentle jogging and single limb heel raises were commenced. By 4 to 6 months, running was introduced and strength and distance activities progressed (Table 1).

Our University hospital is the only hospital in our region which serves approximately 177,000 people spread over a large geographical area. All patients diagnosed with this

injury are seen in our department. Major complications such as deep wound infection or re-rupture would therefore return to our institution. It is possible that some patients may have presented elsewhere with complications after their final clinical review. However, the major complications of re-rupture and wound complications typically present within the first 3 to 6 months of injury.

Statistical analysis was performed with the help of a biostatistician. Two sample t-tests or a contingency table chi square test were used for statistical analysis. This study has been given ethical approval by our regional ethics committee.

RESULTS

There were 363 patients in the 8.5-year period giving an approximate incidence of the injury of 24 per 100,000. There were 197 males (54%) and 166 females (46%). This gives an incidence of approximately 26 per 100,000 males and 22 per 100,000 females. There was an equal sex distribution up to age 50 but there were significantly more males (73%, $p = 0.0007$) in the age group 51 to 60 years. The mean age of males was significantly higher than females [41.2 years (SD, 9.6) v 37.6 years (SD, 9.3), $p = 0.0004$] (Table 2).

Details of the mechanism of injury are given in Table 3. A total of 285 (78.5%) of the injuries occurred during sporting activities. The incidence of sport related injury at 94% was significantly higher in the 15-to-30-year group than all other groups (all p values less than 0.031). In the group aged 51 to 60 years sports only accounted for 43% of injuries which was significantly lower than the other age groups ($p < 0.0001$). Netball was the most common mechanism accounting for 24% of all injuries, 31% of sporting injuries, and 54% of women aged 15 to 40 years. Only two ruptures in the entire group (0.6%) were considered work related injuries; one in a nurse restraining a patient and one in a farmer.

Of the 363 patients, 143 (39%) were treated operatively and 220 (61%) nonoperatively. The operative group was significantly younger than the nonoperative group (mean age 37.4 years versus 40.9 years, $p = 0.0011$). There was no significant difference in the proportion of males and females treated operatively ($p = 0.168$).

The mean operative time was 52 minutes. There was a mean delay of 0.7 days between admission and operation and a mean stay of 2.4 days. Orthopaedic registrars (surgeons in training) performed the procedure in 114 of 143 cases (80%).

There were two major wound complications requiring repeat surgery. A 36-year-old man had a chronic discharging sinus requiring debridement 16 months after repair. A 47-year-old man required debridement for recurrent infection also at 16 months post-surgery. Both these patients had been repaired using a large non-absorbable core suture in error by registrars contrary to our usual practice. Four patients had minor wound complications. A 57-year-old male required oral antibiotics for a superficial wound infection which healed without further problems. Two patients had minor stitch reactions which healed without antibiotic therapy and a 26-year-old male had an erythematous wound with delayed healing until 8 weeks.

There were 21 re-ruptures (14 male, 7 female) in the 363 patients (5.8%) at a mean time of 70 days (Table 4). In the surgical group there were two re-ruptures of 143 patients (1.4%). A 20-year-old female medical student re-ruptured after 72 days while dancing on a table. A No. 1 absorbable core suture had been used. The other occurred in a 45-year-old man who was jumping into the physiotherapy pool unsupervised at 89 days post-repair. No core suture had been used. There were 19 re-ruptures of 220 patients treated nonoperatively (8.6%). Nine occurred within 8 weeks and typically involved a minor injury. Two occurred around 10 weeks and six occurred between 12 and 14 weeks with a more significant force including three who had returned to sport despite advice. However, two occurred at 4 to 5 months with more minor trauma. Compliance with the rehabilitation guidelines was generally good but worse in males. Twelve re-ruptures occurred in the 144 patients treated nonoperatively by community physiotherapists (8.3%) while six occurred in the 76 nonoperative patients seen in our hospital physiotherapy department (7.9%, no significant difference). All re-ruptures were treated operatively. A 35-year-old male re-ruptured at 28 days following nonoperative treatment and sustained a second re-rupture 68 days following operative repair. A 31-year-old man had a deep infection 10 days following repair of a re-rupture at 20 weeks. This required debridement and a subsequent late reconstruction with a gastrocnemius fascia turndown.

The reoperation rate in the surgical group (four of 143, 2.8%) was significantly lower than in the nonoperative group (19 of 220, 8.6%) ($p = 0.026$). The difference between re-rupture rates in the surgically treated patients and nonoperative patients is significant ($p = 0.004$). This was also the case for male patients ($p = 0.005$). However, in females the difference did not reach significance with the numbers available ($p = 0.23$).

Details of re-ruptures in nonoperatively treated patients are given in Table 5. The re-rupture rate for nonoperatively treated injuries was significantly higher in patients less than 40 years old (13 of 199, 13.1%) compared with those over 40 years (six of 119) (4.1%) ($p = 0.035$). There was also a significantly higher rate of re-rupture in males 40 years and under treated nonoperatively (eight of 44) (18.1%) when compared to females over 40 treated nonoperatively (one of 50) (2%) ($p = 0.008$).

DISCUSSION

The incidence of Achilles tendon rupture varies in different countries but appears to be increasing.[10,16,22,25] The incidence in our region is approximately 24 per 100,000 which compares with reported rates from 9.9/100,000 in Canada,[25] 19.0 per 100,000 in Finland[22] and 37.3 per 100,000 in

Table 2: Details of Patients by Age Bands, Gender, Treatment and Reruptures

Age (yrs)	Total	Male (%)	Female (%)	Sports	Operative				Nonoperative			Reruptures		
					Total	Male	Female	Reruptures	Total	Male	Female	Total	Male	Female
15–30	71	33 (46%)	38 (54%)	67 (94%)	39	16	23	1 (f) (2.6%)	32	17	15	4 (12.5%)	3 (17.6%)	1 (6.7%)
31–40	118	56 (47%)	62 (53%)	98 (84%)	49	29	20	0	69	27	42	9 (13%)	5 (15.4%)	4 (9.5%)
41–50	122	70 (57%)	52 (43%)	97 (80%)	39	26	13	1 (m) (2.3%)	83	44	39	4 (4.8%)	3 (6.7%)	1 (2.6%)
51–60	52	38 (73%)	14 (27%)	23 (43%)	16	13	3	0	36	25	11	2 (5.6%)	2 (8%)	0 (0%)
Total	363	197 (54%)	166 (46%)	285 (78.7%)	143	84	59	2 (1.4%)	220	113	107	19 (8.6%)	13 (11.5%)	6 (5.6%)

Table 3: Mechanism of Injury of Patients with an Acute Achilles Tendon Rupture

Sport	Number	Percentage	Non-sporting mechanism	Number	Percentage
Netball	88	24%	Falls, slips	23	6.3%
Squash	32	8.8%	Pushing car	11	3.0%
Tennis	20	5.5%	Hopping, jumping	10	2.75%
Rugby	19	5.2%	Shifting furniture	3	1%
Soccer	19	5.2%	Walking	3	1%
Dancing	19	5.2%	Lifting	3	1%
Basketball	18	5.0%	Other	5	1.4%
Touch rugby	17	4.7%	Work related	2	0.6%
Badminton	11	3.0%	**Total non-sports**	**60**	**16.5%**
Running	11	3.0%	**Not recorded**	**18**	**5%**
Sports (other)	31	8.5%			
Total Sports	**285**	**78.5%**			

Table 4: Details of Patients Who Sustained a Rerupture

Gender	Age	Original Treatment	Method of rerupture	Days to rerupture	Complications
Female	28	Nonoperative	Vacuuming in CAM walker	42	Sural nerve entrapment
Female	32	Nonoperative	Fall into hole	53	
Female	38	Nonoperative	Foot in gutter	47	
Female	38	Nonoperative	Pushing off	86	
Female	40	Nonoperative	Hopped off bed	72	
Female	42	Nonoperative	Tripped on bedclothes	113	
Male	21	Nonoperative	Walking	50	
Male	25	Nonoperative	Running	83	
Male	30	Nonoperative	Touch rugby	96	
Male	31	Nonoperative	Tripped	140	Deep infection following repair, late reconstruction
Male	35	Nonoperative	Fall into hole	56	
Male	35	Nonoperative	Walking in CAM walker	28	Second rerupture following operative repair at 68 days
Male	37	Nonoperative	Pushed in street	55	
Male	37	Nonoperative	Not recorded	85	
Male	41	Nonoperative	Hockey	87	
Male	47	Nonoperative	Shifting sheep	90	
Male	49	Nonoperative	Tripped	26	
Male	55	Nonoperative	Gentle dorsiflexion	34	
Male	57	Nonoperative	Climbing onto truck	70	
Female	20	Surgical	Dancing	72	
Male	45	Surgical	Jumping into pool	89	

Denmark.[10] Sporting activities are the cause of the injury in 73 to 83% of cases in most series[4,10,25] with ball or racquet sports most common. The rise in incidence appears to reflect the increased participation in sports in recent decades.[10] We found a decreasing rate of sports related ruptures with age with less than half of those aged over 50 sustaining the injury with sporting activity.

The mean age of 40.6 years for our patients is similar to other series which range from a mean of 37 to 45 years.[3,10,18,20,21,28,29] However in our series females were, at

Table 5: Details of Patients Treated Nonoperatively Who Sustained a Rerupture, Sub-divided by Age and Gender

	≤40 years	>40 years	Total
Male	8/44 (18.1%)	5/69 (7.2%)	13/113 (11.5%)
Female	5/57 (8.8%)	1/50 (2%)	6/107 (5.6%)
Total	13/99 (13.1%)	6/119 (4.1%)	19/220 (8.6%)

There is a significantly higher rerupture rate in patients less than 40 years old compared with those over 40 years old (chi square 4.44, $p = 0.035$). Females less than 40 years old have a lower rerupture rate than males less than 40 years old (chi square 7.08, $p = 0.008$). No other differences reached significance.

37.6 years, on average significantly younger than males by 3.6 years. Previous studies from Canada,[25] Scotland,[16] and Finland[21] have reported that women who sustained ruptures were on average 2 to 3 years older than men.

In most epidemiological studies there are 75% to 80% males[10,21,25] with treatment studies comprising 79% to 94% males.[3,6,15,18,20] Our series is unusual in that there were equal numbers of males and females up to age 50. The incidence in women was at least three to four times that reported in Denmark, Canada, and Scotland.[10,21,25] This difference is explained by netball which is played widely and almost exclusively by women at a competitive level although there are mixed social leagues. In netball players jump to catch the ball but are not allowed to step after landing. In Australia a study of injuries in netballers and basketball players showed that TA rupture was common in women with an average age of 35.2 years.[7]

TA rupture is very unusual in under-20-year-olds both in the general population[10,21] and in netballers.[9] Secondary school age netballers make up approximately half of our netball playing population yet there were only two ruptures in that age group. The average age suggests that it occurs in those players returning to the sport after a lay off.

The treatment of Achilles tendon rupture has always been contentious. It is unclear whether functional outcomes are improved after surgery.[3,17,18,20,27,30] Operative treatment usually has a lower re-rupture rate than nonoperative treatment but may have significant wound complications which tend to offset the complication rate.[3,20,28]

Meta-analyses have shown that the re-rupture rate following surgical repair was 3.1% to 3.5% with an infection rate of 4% to 4.7%. The re-rupture rate with nonoperative treatment was significantly higher at 12.6% to 13%.[1,14]

Despite careful technique, more recent papers continue to show re-rupture rates in surgically treated patients from 4.5 to 5.6%[22,23,24] and infection rates of 2.2 to 6%.[22,24] Younger patients may be more prone to re-rupture with Rettig et al.[23] reporting four re-ruptures of 24 (16.6%) in patients less than 30 years of age treated surgically.

Bruggeman et al. reported a wound complication rate of 10.4% in 167 consecutive open repairs with tobacco and steroid use, diabetes and female sex being significant risk factors.[2] We are cautious in operating on older patients, diabetics, smokers and patients on corticosteroids which may help explain the low rate of major wound problems (1.4%) in our operative group. We believe that our operative technique of no tourniquet or self-retaining retractors, absorbable sutures, and perioperative antibiotics also contribute to our low rate of wound complications. Our rerupture rate in surgically treated patients was also low with the use of absorbable sutures whether or not a core suture was used.

Percutaneous techniques may reduce wound infection rates to 0% to 1.8%.[6,8,15] However, re-rupture rates of 2.5% to 7.1% may be higher than with open techniques.[6,8,15,17] Other problems such as palpable knots[8] and sural nerve injury rates up to 10.5% have also been reported.[6,8]

With traditional nonoperative treatment of 8 to 12 weeks in an equinus cast, re-rupture rates as high as 17 to 20.8% have been reported.[18,31] However, this may be reduced to 7% using 8 weeks casting but allowing immediate weightbearing.[12]

In recent years there has been a trend towards functional bracing both following surgery[5,13,19] and in nonoperative treatment.[11,29] This may increase patient satisfaction, lower re-rupture rates and decrease postoperative complications.[26]

Our program was designed to be used consistently and balance early mobilization with protection from patient noncompliance. We only commence weightbearing as tolerated at 4 weeks. Our re-rupture rate of 8.6% in nonoperatively treated patients is comparable to the published results of functional nonoperative treatment. Wallace et al. reported complete (three) or partial (five) re-ruptures in eight of 140 (5.7%) using a nonoperative protocol similar to ours with a custom orthosis from 4 weeks.[29] Hufner et al. reported re-ruptures in eight of 125 (6.4%) with functional nonoperative treatment using ultrasound to determine whether there was a gap of less than 10 mm.[11] The highest rates of re-rupture in our series were seen in males under 40 years. This may reflect the higher demand, greater muscle bulk or lack of compliance likely in this age group. Despite the relatively good results of nonoperative treatment we still found a significantly decreased rate of re-rupture and of reoperation for all causes in our surgical group. There was, however, no significant difference in re-rupture rates for women due to the low rates of re-rupture with nonoperative treatment in women over 40 years old.

There are weaknesses to our study. It is a retrospective audit with no randomization and focused on the end-points of re-rupture and deep infection. Minor complications in either group may be under-reported. However, over the period surgical techniques did not change and the rehabilitation protocol was the same for both groups. It is simplistic to believe that one treatment, either operative or nonoperative, should be used for all patients with this injury. Our selective

approach has resulted in a low rate of surgical complications and a total re-rupture rate of 5.8%. Our series is one of the larger reported yet it may still be underpowered to detect significant differences in risk factors for re-rupture such as age and sex. A future study based on these results with 80% power to detect a difference in re-rupture rates between sexes would require over 600 patients per group.

CONCLUSION

Contrary to previous studies we found an equal number of men and women with an acute Achilles tendon rupture up to age 50 years and a mean age in women of 37.6 years which is 3.7 years younger than men. The unusually high incidence in women appears to be due to the popularity of netball. With our functional bracing protocol there was a significantly lower re-rupture rate in operatively treated patients and a low major surgical complication rate. Our results support surgery in patients less than 40 years of age, in particular males, if there are no contraindications. However, functional bracing, as part of nonoperative treatment can result in low re-rupture rates in patients over 40 especially in females.

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Functional Outcome of Acute Achilles Tendon Rupture With and Without Operative Treatment Using Identical Functional Bracing Protocol

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Abstract

Background: The purpose of this study was to compare the functional results of operative and nonoperative treatment of acute Achilles tendon rupture using an identical rehabilitation program of functional bracing.

Methods: Over a 10-year period, 200 patients (99 operative, 101 nonoperative) aged between 18 and 65 years were treated at our institution's physiotherapy department after acute Achilles tendon rupture. There were 132 patients (62 operative, 70 nonoperative) available for a minimum 2-year follow-up (average 6.5 years; range, 2-13 years). Functional outcome was assessed using the Achilles tendon total rupture score (ATRS).

Results: With the numbers available, no significant difference could be detected in ATRS between operative (mean 84.8, median 90) and nonoperative groups (mean 85.3, median 91; $P = 0.55$). No significant difference could be detected in ATRS between male and female patients however treated ($P = 0.30$) or between patients younger and older than 40 years at time of injury ($P = 0.68$). There was no correlation between ATRS score and age at injury in all patients ($\rho = -0.0168$, $P = 0.85$). In male patients, there was a weak trend with older patients at follow-up having better scores ($\rho = 0.21$, $P = 0.069$). However, among female patients, there was a significant negative correlation between ATRS scores and increasing age ($\rho = -0.29$, $P = 0.03$). Logistic regression analysis failed to show any significant effect of age at rupture, gender, or mode of treatment on ATRS.

Conclusions: This study showed no significant difference detectable in ATRS between operative and nonoperative patients in the treatment of acute Achilles tendon ruptures using an identical rehabilitation program with functional bracing.

Level of Evidence: Level II, prospective comparative study.

Keywords: ATRS, Achilles tendon rupture treatment, functional bracing

Acute rupture of the Achilles tendon is a relatively common injury. The mechanism of Achilles tendon rupture is usually traumatic injury during a sporting event.[6,7,31] It is more common in men, most commonly around 40 years of age. The incidence may be increasing as aging adults continue their participation in high-demand sports.[6,11,20]

There is much debate on the best management of acute Achilles tendon ruptures. Historically, studies have shown increased rerupture rates with nonoperative management, which are typically 9% to 12%[15] and may be as high as 21%.[21] However, there are increased wound-healing problems with operative treatment, which can be catastrophic.[10,32] Proponents of surgery cite improved outcomes with surgery, and it is recommended for elite athletes.[17,19,31] However, this may be as a result of an accelerated rehabilitation program, which can also be incorporated into a nonoperative functional bracing protocol.[8] These programs have improved early functional outcomes and are safe and have improved patient satisfaction.[18,19,28,30] Recent prospective, randomized studies have failed to show significant clinical differences in functional outcome but continue to show increased wound complications with operative management.[14,33] Regardless of treatment choice, long-term functional deficits may persist in the injured limb.[16,24,27]

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Our hypothesis was that there would be no significant difference in patient-reported functional outcomes between patients treated operatively or nonoperatively when using an identical functional bracing protocol. The purpose of the study was to measure patient-reported outcomes using the Achilles tendon total rupture score (ATRS)[4,23] between 2 cohorts of patients with acute Achilles tendon rupture receiving either operative or nonoperative treatment using the same functional bracing protocol.

Methods

This was a cohort study comparing patient-reported outcomes between operative and nonoperative treatment using an identical functional rehabilitation program. Our regional ethics committee gave approval for the study. Operative or nonoperative treatment was individualized based on patient factors including age, activity level and comorbidities, and surgeon preference. Relative contraindications to surgery were diabetes, tobacco or steroid use, or peripheral vascular disease. A younger, high-demand patient or delayed presentation over 24 hours were relative indications for surgery.

A total of 200 patients met the inclusion criteria of a complete, traumatic closed rupture of the Achilles tendon in patients aged between 18 and 65 years. Ninety-nine patients were treated operatively, and 101 patients were treated nonoperatively. Sixty-eight patients were lost to follow-up because of change of contact number, they moved, or they were not available for the study, leaving 132 patients available for a minimum 2-year follow-up (average 6.5 years, range, 2-13 years; Figure 1). Sixty-two patients (47%) had been treated operatively and 70 patients (53%) nonoperatively. In the study group, of the 132 patients evaluated, the mean age at injury was 41.1 years. There were 79 men (60%) and 53 women (40%). The mean age of women was significantly lower than males by 4 years ($P = 0.044$).

Only patients who were treated in our physiotherapy department were included to ensure consistency of the use of the rehabilitation protocol (Table 1). Patients were excluded if their rehabilitation occurred outside our institution. Chronic ruptures, partial ruptures, tendinosis, and gastrocnemius tears were also excluded. The diagnosis was based on clinical examination. We did not routinely use ultrasound or magnetic resonance imaging (MRI) in the diagnosis or management of acute ruptures.

Operative Technique and Treatment Protocol

Surgery was performed with the patient prone with a single preoperative dose of intravenous 2 g cefazolin. Tourniquets or self-retaining retractors were not routinely used. A short posteromedial incision was made over the defect. A Kessler type 1 core suturing technique with absorbable No. 1 suture and multiple interrupted 3/0 absorbable sutures was used to braid the periphery together. The paratenon was closed with an absorbable suture and skin closed either with interrupted nylon skin sutures or a subcuticular absorbable suture. Postoperatively, the ankle was placed in an equinus cast. Patients in the nonoperative group were placed in a below-knee cast with ankle in full gravity-assisted equinus.

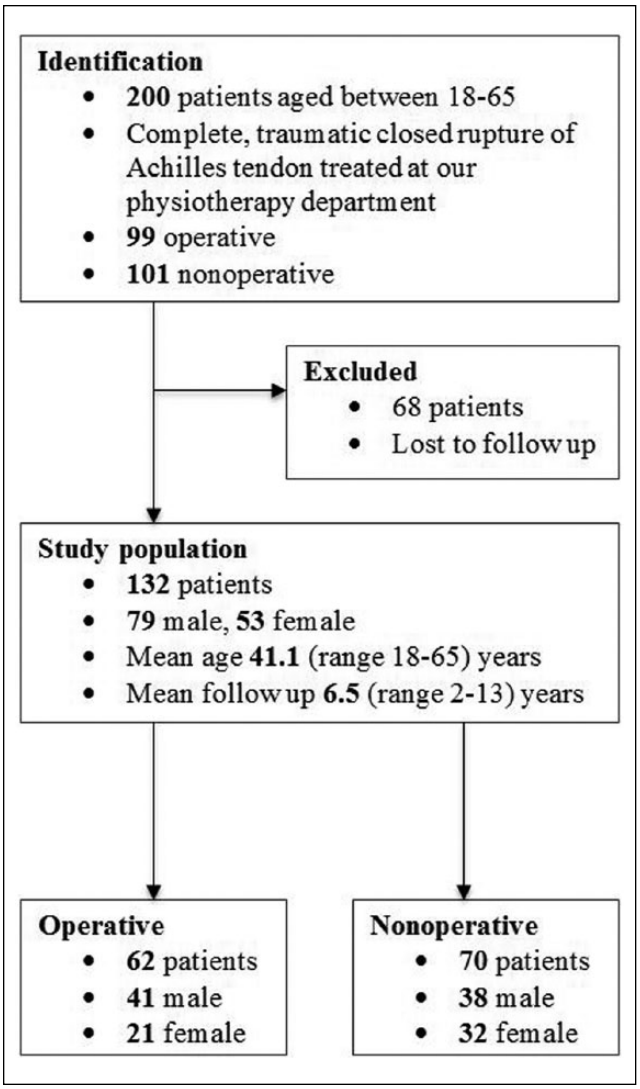

Figure 1. Diagram showing identification of the study population, inclusion and exclusion criteria, and the study groups.

The patients in both groups were kept non–weight bearing in a cast for 4 weeks and then placed in a controlled ankle movement walker boot (Tukwila, WA) locked at 20 degrees equinus and worn day and night. Physiotherapy treatment then commenced with the equinus progressively decreased to neutral by 6 to 8 weeks. Weight bearing progressed from partial to full as patient tolerance and range of motion allowed. This was usually once the equinus was reduced to 10 degrees or less. The orthotic was removed by

Table 1. Rehabilitation Protocol Used by Our Physiotherapy Department Following Operative Repair or Nonoperative Treatment.

0-4 wk	• Relaxed equinus cast non–weight bearing
Phase 1	• Active only range of motion with knee bent and straight
4-8 wk	• Gait reeducation in controlled ankle movement walker increase from partial to full weight-bearing
	• Isometric calf exercises
	• Introduce pool
	• Manual therapy
Phase 1	• Light concentric
8-10 wk	• Passive stretches/lying/sitting
	• Bilateral calf raises
10-12 wk	• Bilateral calf raises non–weight-bearing (ie, sitting)
	• Cycling with heel flat
	• Heavy concentric–bilateral calf raise
	• Light eccentric
	• Proprioception
Phase 3	• Single-leg raises
12-16 wk	• Progress concentric/eccentric
	• Jogging
	• Progress cycling
	• Proprioception
Phase 4	• Progress speed, distance of activity
4-6 mo	• Running
	• Plyometric

8 weeks. Phase 2 from 8 to 12 weeks included active and passive stretches, concentric and eccentric muscle strengthening, and proprioception. Aqua jogging, increasing weight bearing, and cycling with heel flat were allowed. After 3 months, gentle jogging and single-limb heel raises were commenced. By 4 to 6 months, running was introduced and strength and distance activities progressed (Table 1).

Prospectively gathered data included demographic details including age and gender. Chart review was performed, and our audit database was checked for details of complications, reruptures, and reoperations. Patients were contacted for review by mail, telephone, and online surveys, which included the ATRS. The ATRS is a validated patient-reported outcome score published in 2007 by Nilsson-Helander et al.[23] It consists of 10 questions in which the patient self-reports the amount of limitations on each particular aspect of the function of the Achilles tendon giving a 0 to 100-point linear score, with 100 being a normal functional Achilles tendon. A 7 to 10-point difference is considered clinically relevant.[3,4,23]

The primary outcome of this study was to compare the patient-reported functional outcome using the ATRS between the operative and nonoperative groups. Subgroup analysis was performed comparing gender and age of patients within and between the 2 groups.

Statistical Methods

All statistical data were calculated using the statistical software Stata (StataCorp, www.stata.com). An intention-to-treat analysis was performed. Therefore, patients initially treated nonoperatively who reruptured and required surgery were analyzed as nonoperative treatment. Statistical significance of the functional scores between the 2 groups was analyzed with the use of a 2-sample Wilcoxon rank-sum (Mann-Whitney) test. A χ^2 test was used to compare rerupture rates. Spearman's ρ was used to investigate the association between ATRS and age and follow-up duration. A logistic regression analysis was performed to explore the effect of age at rupture, gender, and mode of treatment on ATRS.

Results

Of the 99 patients treated operatively, there were 2 reruptures (2%). Of the 101 patients treated nonoperatively, there were 6 reruptures (6%). There was no statistically significant difference in rerupture rates between treatment groups ($\chi^2 = 2$, $P = 0.157$). There was no significant difference in age between the operative and nonoperative groups ($P = 0.3$; Table 2).

There was no significant difference in ATRS functional scores between operative (mean 84.8, median 90) and nonoperative groups (mean 85.3, median 91; $P = 0.55$) with the numbers available. There was no significant difference in scores between the two treatment groups seen for either men or women (Table 2) There was no significant difference in mean ATRS between men and women however treated ($P = 0.30$) or between patients younger and older than 40 years at time of injury ($P = 0.68$; Table 2).

There was no correlation between ATRS score and age at injury in all patients ($\rho = -0.0168$, $P = 0.85$). In male patients, there was a weak trend with older patients at follow-up having better scores ($\rho = 0.21$, $P = 0.069$). However, among female patients, there was a significant negative correlation between ATRS scores and age at follow-up, with older patients tending to have poorer scores ($\rho = -0.29$, $P = 0.03$). These trends were also seen when comparing age at rupture: men ($\rho = 0.18$, $P = 0.11$), female ($\rho = -0.35$, $P = 0.011$). The duration of follow-up had no relationship to ATRS ($\rho = 0.14$, $P = 0.1$). Logistic regression analysis failed to show any significant effect of age at rupture, gender, or mode of treatment on ATRS.

Discussion

The use of accelerated functional rehabilitation in operative or nonoperative treatment of Achilles ruptures is increasingly common. The protocols usually combine both early weight bearing and early motion in an orthotic rather than

Table 2. Details of Patients, Treatment, and Achilles Tendon Rupture Score (ATRS).

	Number	Mean Age, y	ATRS Mean	ATRS Median	Interquartile Range
All patients	132	41.1	85.1	91	78, 98
Male	79	42.7	87.7	91	82, 98
Female	53	38.9	81.2	91	71-97
Operative	62	40.1	84.8	90	78, 98
Male	41	41.5	85.5	89	78, 98
Female	21	37.3	83.5	91	77, 97
Nonoperative	70	42.0	85.3	91	80, 98
Male	38	43.9	90.1	93	87, 99
Female	32	39.8	79.6	87	60, 99

conventional casting. These may result in lower rerupture rates and earlier functional gains compared with the results with traditional casts.[7,18,26,28,29,33] A recent meta-analysis by Soroceanu et al[29] concluded that functional outcome scores did not differ significantly between the 2 groups. However, variability in treatment protocols and in the use of validated and nonvalidated scores means results need to be treated with caution.[10] We sought to minimize this variation by using identical casting, bracing, and rehabilitation guidelines with all patients followed in our physiotherapy department. The protocol was developed in 2001 to try to balance early motion with protection from noncompliant patients and is not as aggressive as many published studies.

This study uses the ATRS as it has been identified as the only outcome measure that has demonstrated multiple facets of validity for use in this patient group.[13] Healthy patients have scores close to 100, and a score of 85 points and above is considered a good or excellent result.[3,23] Most studies have reported mean ATRS scores of 80 to 90 at 12 months, with median scores around 90 regardless of treatment.[12,25] However, Barfod et al[1] in a randomized controlled trial (RCT) comparing the effect of early weight bearing in patients managed nonoperatively reported a mean ATRS of 73 and 74 at 12 months. It is not clear why their scores were lower. The mean age of their patients was similar to ours, although there were only 16% women. The largest study we are aware of using the ATRS surveyed 487 patients at mean 3.6 years postinjury.[2] There was no significant difference in ATRS between operative treatment at one hospital (81.7) and nonoperative treatment at another (78.9). The mean age of their cohort was 46 years, which is 5 years older than our study.

To our knowledge, there have been only 2 RCTs comparing functional outcome scores of operative versus nonoperative treatment using the ATRS.[22,25] Neither showed any significant difference in ATRS at 12-month follow-up. In an RCT of 97 patients, all underwent an identical bracing and mobilization program.[22] The mean 12-month ATRS and rerupture rates were 88 points and 4% for the operative and 86 points and 12% for the nonoperative group. Olsson et al[25] reported the mean 12-month ATRS was 82 in the operative group and 80 in the nonoperative group. Our results are comparable to these studies[22,25] but at a longer-term mean follow-up of 6.5 years. The mean and median ATRS results suggest a good or excellent result in most patients regardless of treatment. Our rerupture rates of 2% in the operative group and 6% in the nonoperative group are lower than those reported in meta-analyses.[10,29,32] The difference in rerupture rate failed to reach statistical significance, which is probably due to small numbers. We identified no significant functional benefit from operative treatment in any subgroup of age or gender with the numbers available.

In other RCTs comparing operative and nonoperative treatment, Keating and Will[14] found no functional differences at 1 year using a traditional casting approach but had rerupture rates of 5% and 10%, respectively. Moller et al[21] had an unacceptably high rerupture rate of 20.8% with nonoperative treatment but had equally good functional results if complications were avoided. Metz et al[19] compared minimally invasive surgery with nonoperative treatment but used differing rehabilitation protocols and braces. There was an earlier return to work in the surgery group, but no other differences reached significance. Willits et al[33] used an identical bracing and rehabilitation program in an RCT of 144 patients. Rerupture rates were not statistically significant (2.8% operative, 4.2% nonoperative), and there were no functional differences using both objective measures and the Leppilahti score.

Hutchison et al[9] have recently reported a large series of a dedicated management programs using ultrasound to determine treatment, functional bracing, early weight bearing, and an accelerated exercise program. Their rerupture rate is the lowest we are aware of in a large series, with only 3 of 273 (1.1%) overall and 2 of 211 (1%) treated nonoperatively. Their ATRS scores were collected only to 9 months in 43 patients and so were relatively low at 72.4. The ATRS typically improves to 12 months and may improve with nonoperative management until 2 years.[24] The program resulted in a significant reduction in surgery and health care costs, with satisfactory outcomes.

It is not clear why there was a negative association between age and ATRS in female patients with the opposite

trend in male patients in our study. Women in our study tended to have lower scores than men, particularly with nonoperative treatment, where the difference in mean score was 10 points. While this did not reach statistical significance, it may be clinically relevant. Grävare Silbernagel et al[5] also noted lower scores in women, but the differences did not reach significance. Bergkvist et al[2] reported a significant worsening of ATRS with increasing age in nonoperatively managed female patients. The demographics of our study population were unusual in that there were a high proportion of women (40%) compared with studies from other countries, and the female patients were typically 4 years younger at the time of injury than male patients. The gender difference should be recognized in future studies.

Limitations of the Study

There are limitations to our study. It is a cohort study with no randomization and focused on the ATRS score as the primary outcome. However, the 2 groups were well matched with respect to numbers, age, and gender. We did not use other objective tests of strength or record return to work or sport; however, these objective deficits would be expected to show up in a patient-reported score such as ATRS. Other studies have reported objective functional deficits despite good or excellent patient-reported scores.[16,24,27] A strength is that despite a large loss to follow-up, because of a relatively young and mobile population and the long-term follow-up period, the numbers at final follow-up were still larger than most of the studies cited above.[1,14,21,22,25,33] We did not perform a power study prior to commencing the study, but as the ATRS scores were identical in the 2 groups, we believe that the numbers were sufficient to conclude that there was no clinically relevant difference. Strengths of the study were the standardization of the rehabilitation program between the operative and nonoperative groups. It is the longest follow-up study using the ATRS, suggesting that results do not deteriorate with time following injury.

Conclusion

With the numbers available, this study found that there was no statistically significant difference and no clinically relevant difference in patient-reported functional outcomes at minimum 2-year follow-up using the ATRS between operative and nonoperative treatment of Achilles tendon rupture with an identical functional rehabilitation program. It does not support operative treatment of an acute Achilles tendon rupture to improve a patient's functional outcome.

Declaration of Conflicting Interests

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Chapter 5

Scoring, prioritisation and effects of rationing with respect to total joint replacement.

a) Scoring Tools: Implementation & Validation

In publicly funded health care systems there will never be sufficient capacity for all the elective orthopaedic surgery that could be done. How this is managed will vary between health care systems. In New Zealand, Elective Surgery Performance Indicators (ESPIs) have driven the need for scoring or prioritisation tools. If a patient cannot be seen within 4 months of acceptance of a referral, or undergo surgery within 4 months of the decision to offer surgery then they cannot be given certainty and are allowed to be declined. While the Ministry of Health uses the term prioritisation, we have termed this 'explicit rationing' which has achieved a degree of acceptance in the media. A variety of scoring tools for surgical prioritisation have been used in NZ since the introduction of Clinical Priority Access Criteria (CPAC). It is expected that these prioritisation tools are used in all DHBs. However, threshold scores, which may allow comparison between DHBs, are not publicised and are not released by the Ministry of Health. The lack of consistency in scoring within and between DHBs is cited as a reason for this. There has been limited validation of these tools and little comparison with widely used condition-specific patient reported outcome scores.

As part of the Orthopaedic Patient Programme we implemented independent nurse led scoring for hip and knee replacement due to concerns regarding the impartiality of surgeon scoring. In '*Rationing for Total Hip and Knee Arthroplasty Using the New Zealand Orthopaedic Association Score: Effectiveness and Comparison with Patient-Reported Scores'* we report on the NZ Orthopaedic Association score for hip and knee replacement and its comparison with established validated condition-specific patient-reported scores such as the Oxford Hip and knee score. We found the score to be effective tool for rationing joint replacement but had concerns about its ability to discrimate around the threshold score. In '*The ShortMAC: Minimum important change of a reduced version of the WOMAC osteoarthritis index' w*e investigate the minimum important clinical change in a shortened version of the Western Ontario MacMaster (WOMAC) osteoarthritis Index. We conclude that it is valid and responsive and a patient friendly alternative to the traditional tool.

Some centres match their acceptances for FSA to their likely surgical capacity rather than using surgical prioritisation. This has led to the development of a new tool, the National Referral prioritisation tool (NRPT), to prioritise referrals so that the rationing is performed at an earlier stage before a patient is even seen at FSA. It has been designed to be a generic tool that can be used for all specialities. We have been the first to pilot the NRPT in Dunedin where it was introduced to try to reduce the acceptance rate of referrals by 50%.

In *'The National Referral Prioritization Tool for First Specialist Assessment: Results of the Pilot Study in Orthopaedic Surgery"* we report the results of the pilot implementation of the new NRPT in orthopaedic surgery in Dunedin. We conclude that it is more discriminating than the clinical priority categories used previously and potentially allows fine-tuning of a threshold score to balance acceptances and capacity.

b) Consequences of rationing

While it has been accepted that there will never be enough capacity for everyone who may benefit from surgery, it has not been documented what the consequences are of explicit rationing both for individual patients who have been declined surgery and for the service. *'Rationing of hip and knee replacement: Effect on the severity of patient-reported symptoms and the demand for surgery in Otago'* showed that the demand for THR/TKR had increased by 19% from my original study. Patients qualifying for surgery were more disabled and many of those that were declined would have qualified for surgery previously.

'The Outcomes of patients returned to General Practitioner after being declined hip and knee replacement' reports on what happen to those patients who are recommended THR or TKR but fail to qualify due to their prioritisation score. There is little else that the GP has to offer so many are re-referred. The majority subsequently undergo surgery with patients with hip OA more likely to qualify than those with knee OA. This merely delays surgery by an average of 15 months while the patient deteriorates. The patients are more likely to be deconditioned which may have an effect on their outcome after surgery.

c) Health Related Quality of Life

The final two papers in this chapter introduce general health related quality of life (HRQoL) scores rather than condition-specific scores. In '*The relationship between preoperative Oxford hip and knee score and change in health-related quality of life following total hip and total knee arthroplasty: Can it help inform rationing decisions?*' we showed that patients with poorer preoperative Oxford hip and knee scores will end up with a poorer post-operative Oxford score and general health related quality of life (HRQoL), as measured by SF-6D utility, but will have a greater gain in HRQoL. The inference is that making a patient wait until they have declined to a threshold score will have a negative impact on their final outcome.

In '*Total Hip and Knee Arthroplasties Are Highly Cost-Effective Procedures: The Importance of Duration of Follow-Up'* we use the SF-6D utility to model cost-effectiveness of hip and knee replacement out to 15 years including long term revision rates and mortality. This shows that both procedures are highly cost-effective by 3 years with the cost/QALY reducing out to 15 years. They are more cost-effective in those with poorer preoperative scores and younger patients but remain highly cost-effective even in older patients and those with better preoperative scores.

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Rationing for Total Hip and Knee Arthroplasty Using the New Zealand Orthopaedic Association Score: Effectiveness and Comparison With Patient-Reported Scores

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ABSTRACT

Background: There is increasing interest in scoring systems to prioritize patients for hip and knee arthroplasty. The purpose of this study was to determine the effectiveness of the New Zealand Orthopaedic Association (NZOA) score and compare it with patient-reported scores of patients listed for hip and knee arthroplasty.

Methods: Over a 1-year period, all patients listed for primary hip and knee arthroplasty were scored by a prioritization nurse. The NZOA score, outcome, preoperative Oxford hip or knee score (OHKS) and reduced Western Ontario McMaster osteoarthritis index (WOMAC) score (RWS) were collected.

Results: Overall, 608 patients were listed for hip (319) or knee (289) arthroplasty. The mean scores for knees were all better than hips ($P < .001$). On initial scoring, 324 patients (53%) were given certainty (mean NZOA, 80.5; OHKS, 10.0; RWS, 35.1), 90 (15%) given clinical over-ride (NZOA, 69.6; OHKS, 12.0; RWS, 33.2), and 194 (32%) returned to general practitioner (NZOA, 64; OHKS, 14.2; RWS, 30.8). Knees (38%) were more likely to be returned than hips (26%; $P = .002$). Fifty (26%) were re-referred during the study period (mean, 5 months) and given certainty or over-ride. The difference at final outcome between patients with certainty and clinical over-ride was NZOA, 10.3 points; Oxford, 1.6 points; and RWS, 1.4 points. The difference between clinical over-ride and returned to general practitioner was NZOA, 7.2; Oxford, 4.4; RWS, 5.3.

Conclusion: The NZOA score is an effective tool for rationing for joint arthroplasty. Patients around the threshold score of 70 may not have a clinically important difference compared with those above threshold.

Hip and knee arthroplasty are 2 of the most successful and cost-effective interventions in orthopedic surgery. However, public health systems are under significant funding constraints, and in our country, it is recognized that there is a need for explicit rationing of publicly-funded total joint arthroplasty. Several scoring systems have been used in the last 15 years in our country: the Clinical Prioritisation Access Criteria score [1], the priority scoring system for major joint arthroplasty (also known as the New Zealand score) [2-4] and the New Zealand Orthopaedic Association Hip and Knee priority score (NZOA score) introduced in 2008 [5,6] (Fig. 1).

As the demand for major joint arthroplasty continues to rise, other countries have developed priotitization scores [7-9]. In the United Kingdom, it has been proposed that the widely used Oxford and Western Ontario McMaster osteoarthritis index (WOMAC) scores should be used to ration access to joint arthroplasty with varying thresholds suggested [10]. However, several authors have reported that these scores do not predict satisfaction post-operatively and should not be used for prioritization [10-13].

The NZOA score has been widely used in our country since its introduction. It has sections on pain, personal functional limitation,

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Criterion	Category	Category Descriptions – Assign patient to highest scoring category that applies *(Patient must be on optimal medical therapy at time of rating)*	Points
Pain	1	No Pain	0
	2	Episodic activity-related pain	
		May use occasional analgesics	4
	3	Daily pain with weight-bearing activity	
		2–3 times/week pm use of simple analgesics/NSAIDs	10
	4	Pain which cannot be ignored with activity and at rest	
		Sleep disturbance 2–3 times / week due to pain	19
		Daily analgesics/NSAIDs	
	5	Dominates life and interferes with sleep every night	
		Pain poorly controlled by analgesics	27
Personal Functional Limitation DUE to Hip or Knee Orthopaedic Condition	1	No Limitation	0
	2	**Minimal restriction of personal activities** e.g. trouble reaching toes	
		Walking stick used for longer walks	3
	3	**Moderate restriction of personal activities** e.g. requires help with socks/shoes	
		Requires help cutting toenails	9
		Use of walking stick indoors and outdoors	
	4	**Severe Restriction of personal activities** e.g. requires help with dressing or showering	18
		Consistently uses 2 crutches or wheelchair	
Social Limitation DUE to Hip or Knee Orthopaedic Condition	1	No Limitation	0
	2	**Mild Restriction** e.g. can't walk >1 hour	4
		Some limitation of leisure activity e.g. golf or tennis	
	3	**Moderate Restriction** e.g. can walk 15–60 mins	
		Significant limitation of leisure activity	10
		Can manage garden or bowls	
	4	**Severe Restriction** e.g. can't walk > 15 mins – slow	
		Difficulty with steps or stairs	
		Severe limitation on leisure activity – can't maintain garden	19
		Requires help with shopping	
		Some limitation to work	
	5	**Profound Restriction** e.g. confined to the property	
		Shopping done by others	
		Requires meals or other domestic help	23
		Can't work due to orthopaedic condition	
Potential to Benefit from Operation (for patient, dependents or community)	1	Small Improvement Likely – significant residual symptoms +/or functional limitation	0
	2	Moderate Improvement Likely – some residual symptoms +/or functional limitation	6
	3	Return to near normal likely – asymptomatic + full return of function	
Consequence of delay >6 months (for patient, dependents or community)	1	Little risk will deteriorate over next 6 months	0
	2	Considerable risk will deteriorate and result in increased disability during next 6 months	7
	3	Likely to progress to major complication during next 6 months with increased clinical costs, e.g. impending fracture or structural failure **Criteria for awarding 24 points for consequence of delay**: Avascular necrosis with collapse of femoral head or supero-lateral acetabular erosion. Large cysts in head, acetabulum or around knee with rapid progression. Major periprosthetic osteolysis with risk of fracture. Severe fixed valgus deformity at knee Lead carer with risk of dependents requiring rest home care. Requirement for rest home level care without surgery (if surgery will reduce the risk) Incipient loss of job (if realistic chance of return to work after surgery)	24

Fig. 1. New Zealand Orthopaedic Association Hip and Knee Prioritisation Tool (NZOA score) including local criteria for determining score for consequence of delay.

social limitation function, ability to benefit, and consequence of delay and is scored 0 (best) to 100 (worst). There has been little published on it and no validation studies. Recently, a study [6] compared the NZOA scores between 2 District Health Boards and showed significantly higher scores at one hospital with 36% of patients declined surgery due to threshold. It was unclear if this represented scoring practice or a true difference in pain and disability. In our district, we have had significant problems with excess demand over capacity [14]. We have used the NZOA score since its introduction. Scoring was originally done by the supervising consultant via a form in the patient's electronic record. Within a short time, the financial threshold score rose from below 70 to 79 points and the numbers of patients failing to meet threshold rapidly increased. When the threshold rose to 80 points, the system broke down as it was almost impossible to score patients above threshold without "gaming" the system. This typically involved the indiscriminate use of 24 points for the question 5 (consequence of delay). As part of a programme, funded by the National Health Board, to address patient flow, it was decided that all scoring for joint arthroplasty surgery in our hospital would be by a single experienced orthopedic nurse to ensure consistency, using the NZOA score.

The purpose of this study was to determine the effectiveness of the first 12-month use of the NZOA score as scored by the prioritization nurse (PN) and to compare the score against validated patient-reported scores for all patients listed for hip and knee arthroplasty whether qualifying for surgery or not.

Methods

In October 2013, before the programme commencing, the threshold for hip and knee arthroplasty in our hospital was 80 points using the NZOA score. As an inter-rater reliability exercise, 103 consecutive patients listed for hip or knee arthroplasty were scored both by a consultant at the time of first specialist assessment and by the PN. Comparisons of the first 4 questions of the NZOA score were made. The inter-rater reliability, or degree of agreement between the consultant and nurse (for each of the 4 questions separately and also the threshold score outcome), was assessed using weighted Kappas (using linear weights).

After analysis of the waiting list figures, capacity, contracted volumes, and Elective Services Performance Indicator compliance, the threshold was set at 71 points commencing November 1, 2013. All patients falling below threshold would be returned to general practitioner (GP) although clinical over-ride could be used. Criteria for the use of 24 points for question 5 were developed after discussion with all surgeons. (Fig. 1)

The letters of patients referred to the Orthopaedic Department by GPs are triaged by a surgeon. Patients with severe symptoms or radiologic changes will be offered an appointment. Others may be referred to a nurse and physiotherapy led clinic, the "Joint Clinic" to maximize nonoperative treatment. Those in need of surgery can then be referred for a specialist appointment. The decision to wait-list a patient is at the surgeon's discretion after assessing the risk-to-benefit ratio for an individual patient. We have no formal policy on patients with increased body mass index. Dietitian advice is offered at joint clinic or at outpatient appointment. The average body mass index of our patients undergoing hip or knee arthroplasty is 31.7kg/M^2. Details of all patients seen and listed for primary hip or knee arthroplasty surgery were collected from November 1, 2013, to October 31, 2014. The patient completed an Oxford hip or knee score (OHKS) and a reduced WOMAC score (RWS). The modified Oxford score (0-48 where 0 is worst and 48 best) was used. [15] The RWS is a shortened version of the original WOMAC score [16] and uses 5 pain questions and 7 function questions (scored 0-4, where 0 is best) giving a worst score of 48 [17].

Patients were phoned by the PN within 2 weeks and scored using the NZOA tool. A decision on whether the patient qualified for publicly funded surgery was made and communicated in writing to the patient. Patients were categorized as: certainty (NZOA score 71 or greater), clinical over-ride (NZOA <71 points), or return to GP (NZOA score <71).

The decision on qualification was deferred if active medical problems such as poorly controlled diabetes, cardiovascular disease, or smoking required addressing first. Reasons for clinical over-ride were collected. Details and scores of patients returned to GP care were collected including their subsequent outcome.

Independent samples *t*-tests were used to compare means, and the test for a difference in proportions was used to estimate the differences between hip and knee patients in outcome (certainty, clinical over-ride, and return to GP). Pearson's correlation coefficient (r) was calculated to examine the correlations between the 3 different scoring methods. The 2-sided significance level $\alpha = 0.05$ was specified for all statistical tests. Stata software, version 13.1, was for all statistical analyses.

Ethics approval was given by the local institutional review board for this study.

Results

In the inter-rater reliability investigation there were 103 patients scored by both the PN and a consultant. The agreement between the consultant and nurse on the 4 individual questions varied from "fair" to "almost perfect" with weighted κ of 0.55, 0.69, 0.27, and 0.89 for questions 1-4, respectively [18]. The mean (standard deviation [SD]) NZOA score by the consultant was 75.6 (9.7) compared with 75.1 (10.60) by the nurse. With a threshold score of 80 points at that time for surgery, the consultant and nurse agreed on 91 (88.3%) of the patients. The consultant scored 7 above threshold where the nurse scored them below and the consultant scored 5 below threshold where the nurse scored them above. The weighted κ assessing the agreement on certainty categorization was 0.71 suggesting "substantial" inter-rater reliability of the NZOA score [18].

During the 12-month period, November 1, 2013, to October 31, 2014, 608 patients were wait-listed for either hip or knee arthroplasty and scored by the PN. These patients had a mean age of 68.3 years (SD 10.5) and 342 (56.2%) were women. Of these, 414 (68.1%) initially qualified for surgery (324 with certainty and 90 patients with clinical over-ride), with the remaining 194 (31.9%) patients returned to GP care (Table 1).

The mean NZOA score for patients with certainty was 80.5 points, which was significantly higher than those on clinical over-ride (69.6) which in turn was significantly higher than those returned to GP care (64 points; $P < .001$). The Oxford score for each category was also statistically significantly different (P values < .001-.019) although the difference in mean score was only 2 points between certainty and clinical over-ride and 2.2 points between clinical over-ride and GP care. The difference in mean RWS between certainty and clinical over-ride ($P = .048$) or GP care ($P < .001$) were both statistically significant.

There were 319 patients listed for hip arthroplasty (52.5%) and 289 (47.5%) listed for knee arthroplasty (Table 2). The mean age of patients listed for hip arthroplasty was significantly lower than knees by 2 years (67.3 years [SD 11.6] vs 69.4 (9.1) years; diff: 2.1; CI: 0.4-3.7; $P = .0157$), and similar proportions of each were female (56%). Hip patients were statistically significantly more likely than knee patients to qualify for surgery at initial assessment either through meeting the threshold (60.8% vs 45.0%; diff: 15.8; CI: 8.0-23.7; $P < .001$) or when those with clinical over-ride are included (73.7% vs 61.9%; $P = .002$). Therefore, knees were significantly more likely to be returned to GP (38% vs 26%; diff: 11.7; CI: 4.3-19.1; $P = .002$; Table 2).

The mean NZOA, Oxford, and RWS scores of all patients listed for joint arthroplasty were significantly worse for hips than knees. Hips given certainty initially had significantly higher mean NZOA scores and RWS than knees with certainty. There was no significant difference between hips and knees in the clinical over-ride and return to GP categories for any of the 3 scores.

The NZOA score as expected showed a significant difference ($P < .001$) between each of the 3 outcome categories for both hips and knees There was a statistically significant difference in mean Oxford and RWS between the certainty and return to GP categories for both hips (Oxford 3.3 points $P < .001$, RWS 4.2 points, $P = .001$) and knees (Oxford 4.5 $P < .001$, RWS 3.7 points, $P = .01$). For knees, the difference in mean Oxford score between certainty and clinical over-ride (1.9 points, $P = .030$) and between clinical over-ride and GP care (2.6 points, $P = .033$) reached significance although the actual differences are small.

The RWS and Oxford scores had very high correlation with each other($r = -0.8058$, $P < .001$), whereas there was a poorer correlation between NZOA and either Oxford ($r = -0.4309$; $P < .001$) or RWS ($r = 0.3391$, $P < .001$).

Of those initially returned to GP, 50 patients (25 hips and 25 knees; 25.8%) were referred back within the study period and subsequently scored above threshold (13) or given clinical over-ride (37). The mean time to the new decision after rescoring was 5

Table 1
Outcomes and Mean Scores of All Patients Waitlisted for Hip or Knee Arthroplasty, After Initial Categorization and After Final Outcome.

Outcome Category	All Patients After Initial Prioritization				All Patients Final Outcome			
	N = 608	NZOA Score (SD)	Oxford/48 (SD)	RWS/48 (SD)	N = 608	NZOA Score (SD)	Oxford/48 (SD)	RWS/48 (SD)
Certainty (NZOA ≥71 points)	324 (53.3%)	80.5 (6.2)[a,b]	10.0 (4.5)[a,b]	35.1 (6.6) [a,b]	337 (55.4%)	79.9 (6.8)[a,b]	10.0 (4.5)[a,b]	35.2 (6.6)[a]
Clinical over-ride (NZOA <71 points)	90 (14.8%)	69.6 (1.8)[a,c]	12.0 (4.7)[a,c]	33.2 (6.5)[c]	127 (20.9%)	69.6 (1.8)[a,c]	11.6 (4.6)[a,c]	33.8 (6.5)[a]
GP care	194 (31.9%)	64.0 (6.8)[b,c]	14.2 (6.1)[b,c]	30.8 (8.4)[c]	144 (23.7%)	62.4 (7.0)[b,c]	16.0 (6.0)[b,c]	28.5 (8.1)[b,c]

NZOA, New Zealand Orthopaedic Association; RWS, reduced WOMAC score; SD, standard deviation; GP, general practitioner.
[a] Statistically significantly different from the corresponding GP care score.
[b] Statistically significantly different from the corresponding clinical over-ride score.
[c] Statistically significantly different from the corresponding certainty score.

months with only 11 patients in this group re-referred after 6 months. The RWS and Oxford sores of these patients were not significantly different from those patients initially given certainty ($P = .316$ and $P = .966$, respectively). The NZOA (diff: 6.2; CI: 4.2-8.2; $P < .001$), Oxford (diff −6.0; CI −8.4 to 3.6; $P < .001$) and RWS (diff 7.9; CI 4.6-11.3; $P < .001$) scores of these 50 patients were significantly worse than the 144 who remained in GP care.

In total, 464 patients (260 hips and 204 knees) were given certainty for surgery during the 12-month period, and of these, clinical over-ride was invoked for 127 (21%) patients. There was no significant difference in the use of clinical over-ride between hips and knees either at initial scoring (hip: 12.9% vs knee: 17.0%; $P = .155$) or final outcome (18.8% vs 23.1%, $P = .185$). The most common reasons for clinical over-ride were for patients who had been on long-term active review, those with very poor Oxford or RWS scores, employment or social issues, second side surgery, or patients with significant medical conditions such as rheumatoid arthritis and hematologic and renal disorders.

At final outcome, the difference in mean scores between the certainty and clinical over-ride categories was 10.4 points on NZOA ($P < .001$) but only 1.6 points on Oxford ($P = .007$) and 1.4 points on RWS ($P = .100$). The corresponding differences in the mean scores between clinical over-ride and GP care were 7.2 points on NZOA, 4.4 points on Oxford, and 5.3 RWS (all $P < .001$; Table 1, Fig. 2).

Discussion

Hip and knee arthroplasty surgery are highly successful and cost-effective interventions but with an aging population the demand is increasing [19]. Funding constraints are likely to become an increasingly widespread problem, both in our country and worldwide, as the population ages and demand outstrips supply. There has been much debate in countries with public health systems about the use of scoring tools to prioritize and ration joint arthroplasty surgery. Should surgery be for those most in need [1], those most likely to be satisfied or have the best outcome [11,13], or those who will gain the most or be the most cost-effective? [10,20,21].

Oxford and WOMAC scores have been widely used as patient-reported scores, but they were not designed to prioritize patients [15]. Despite this, it has been proposed that the Oxford score should be used to ration access to TKR with a threshold OKS ranging from 18 to 32 points [10]. However, neither score has been shown to be predictive of satisfaction mainly because postoperative satisfaction is so high [10,11,13]. Similarly, cost effectiveness studies have shown that the vast majority of hip or knee arthroplasties are cost-effective [10,20] even with Oxford scores up to 35 or 40 if healthy [10]. Hossain et al concluded that the decision to implement knee arthroplasty for a patient should be undertaken individually without reliance on preoperative patient-reported outcome measures [12]. This traditional approach, however, does not appear to accept the need for explicit rationing.

The NZOA score was developed using a process described by Hansen et al [5] and is a development of the previously used Clinical Prioritisation Access Criteria and New Zealand tools [1-4]. There are 5 sections with scores given relative weightings developed during the validation process. It does not include patient-reported scores but has sections on pain, personal functional limitation, social limitation function, ability to benefit, and consequence of delay. Although used by about half of the 20 District Health Boards in NZ there have been no validation studies. The only publication we are aware of using the score is by Blackett et al [6] who compared 2 centers. In Hawkes Bay 41% and in Northland 33% of patients were declined due to threshold. The average NZOA score for patients in Hawkes Bay qualifying for surgery was 76.9 points and for those declined was 64.7 points, whereas in Northland, the scores were 70.6 and 55.4 points. They do not directly state their treatment threshold or use of clinical over-ride. As no other outcome score was used and multiple consultants scored the patients, it is not clear whether the differences seen in their study are true differences in the incidence and severity of disease, surgical capacity, or reflect different interpretations and use of the tool. By using a single nurse to score all patients and also collecting patient-reported outcome measures, we hoped to address these issues.

The WOMAC score has been widely used and has 5 questions for pain, 17 for function, and 2 for stiffness [16]. It may be reported as a total score out of 100 or scored for each domain separately (particularly pain and function). The RWS we have used has 5 pain questions and 7 function questions to give a score of 48 points and more equal weighting of pain and function [17]. We found that the NZOA tool has reasonably good agreement with RWS (correlation coefficient $r = 0.34$) and Oxford scores ($r = 0.43$). The older NZ score was found to have correlations with WOMAC between 0.26 [3] and 0.5 for pain and 0.54 for function [4]. Other scoring systems have correlations with WOMAC between 0.39 and 0.79 [7-9].

The group of patients returned to GP after initial scoring and especially at final outcome scored significantly lower than the certainty group. The difference of 4-6 points on both RWS and Oxford is greater than the minimum clinical difference of 2-5 points reported for the OHKS [15,22] and the 12% change from baseline WOMAC [23] and therefore is likely to be clinically significant.

A concern is the number of patients who were given clinical over-ride either after initial scoring or after return to GP and early re-referral. These patients almost invariably scored 70 points on the NZOA tool. The Oxford and RWS of these patients were less than 2 points different from the certainty group and therefore unlikely to have a clinically important difference.

There is no recognized value of either Oxford or WOMAC score that indicates the need for surgery. In clinical series, authors have reported mean WOMAC scores of 51%-60% [13,24-26]. Gossec et al [27] found WOMAC pain and function scores were predictive of a recommendation of hip (pain 59.8%, function 63.3%) or knee arthroplasty (pain 56.4%, function 59%). This translates to a RWS of

Table 2
Comparison of Scores and Outcomes of Patients Listed for Hip or Knee Arthroplasty.

Outcome Category	Hips, N	Knees, N	NZOA Score				Oxford Hip or Knee Score				Reduced WOMAC Score			
			Hips, Mean (SD)	Knees, Mean (SD)	Difference (95% CI)	*P*	Hips, Mean (SD)	Knees, Mean (SD)	Difference (95% CI)	*P*	Hips, Mean (SD)	Knees, Mean (SD)	Difference (95% CI)	*P*
Certainty ≥71 points	194 (60.8%)	130 (45.0%)	81.6 (6.5)[a,b]	78.9 (5.4)[a,b]	2.7 (−1.4 to 4.1)	**<.001**	9.7 (4.7)[a]	10.7 (4.1)[a,b]	−1.0 (−2.4 to 0.3)	.138	35.9 (6.4)[a]	33.8 (6.8)[a]	2.1 (0.1-4.1)	**.039**
Clinical over-ride	41 (12.9%)	49 (17.0%)	69.6 (1.8)[a,c]	69.6 (1.8)[a,c]	−0.0 (−0.7 to 0.8)	.979	11.3 (5.4)	12.6 (4.0)[a,c]	−1.3 (−3.7 to 1.1)	.291	34.1 (7.0)	32.3 (5.9)	1.8 (−1.6 to 5.1)	.289
GP care	84 (26.3%)	110 (38.1%)	64.6 (6.8)[b,c]	63.5 (6.8)[b,c]	1.1 (−0.9 to 3.0)	.286	13.0 (6.2)[c]	15.2 (5.9)[b,c]	−2.2 (−4.6 to 0.3)	.081	31.7 (8.5)[c]	30.1 (8.2)[c]	1.6 (−1.8 to 5.0)	.360
Total	319	289	75.6 (9.8)	71.4 (9.0)	4.1 (2.6-5.6)	**<.001**	10.7 (5.4)	12.7 (5.2)	−2.0 (−3.2 to −0.9)	**<.001**	34.6 (7.2)	32.2 (7.3)	2.5 (0.9-4.0)	**.002**

Bold denotes statistically significant difference between hip and knee score ($P < .05$).
NZOA, New Zealand Orthopaedic Association; SD, standard deviation; GP, general practitioner.
[a] Statistically significantly different from the corresponding GP care score.
[b] Statistically significantly different from the corresponding certainty <71 points score.
[c] Statistically significantly different from the corresponding certainty ≥71 points score.

Fig. 2. Box plot comparing initial scores with final outcome category. NZOA (New Zealand Orthopaedic Association) score (0 best to 100 worst), Oxford (Oxford hip or knee score 0 worst to 48 best), RWS (reduced WOMAC score 0 best to 48 worst). GP, general practitioner.

28 for knee and 30 for hip which is similar to our return to GP group. In other articles, validating scoring tools, a WOMAC from 39% to 65% for pain and 43% to 58.8% for function qualified for surgery [4,7,9]. Our patients who qualified for surgery would have fallen into the urgent category of Escobar et al (pain 65%, function 74%) [9]. Published series from our country have reported mean WOMAC scores of 56-76 [3,26,28] and Oxford scores in the range 10-18 [28,29].

Hip scores are typically a little worse than knee scores. Gossec reported a difference of 3%-4% in WOMAC pain and function scores between hip and knee patients. Large series from the United Kingdom show an average preoperative Oxford score of 18-20 points for knee arthroplasty [10,11,21,30,31]. The scores for hip arthroplasty are a little lower (worse) at 16-19 points [11,20,21,24,32,33] with public hospital patients scoring worse than private [32].

We found that each of the 3 scores of patients awaiting hip arthroplasty were 4%-5% worse than those waiting for knee arthroplasty. This resulted in significantly more knees than hips being returned to GP. This suggests that patients awaiting knee arthroplasty are disadvantaged relative to those needing hip arthroplasty. However, the gains are usually greater for hip arthroplasty, and it has been suggested that for an equal gain in quality-adjusted life years knee arthroplasties should score 8 points higher than hips on preoperative Oxford score.[21] Both hip and knee arthroplasty are highly cost effective for patients with scores in the range of our patients currently returned to GP [21]. Rationing is delaying surgery for these patients which has significant cost implications for the patient and society, even if not directly to the health system [10,26,34].

A strength of this study is that patient-derived scores were obtained and a single person scored all patients. However, it is possible that patients may have inflated their OHKS and RWS as they realized that honest scoring may result in them not qualifying for surgery. A further weakness is that because of the size of our district and the number of rural clinics, the PN conducted interviews by telephone. However, nurse scoring did correlate well with the surgeon in the pilot study. This study reports on a population that may be skewed by the severity of disease in our region. The average Oxford and RWS scores of those returned to GP were above the mean scores of most series. Therefore, our findings may not be generalizable. Further validation work should look at the effectiveness of the NZOA tool across a wider range of scores.

Many surgeons may find the idea of explicit rationing unacceptable. It is difficult to deny patients surgery that is often life

transforming. However, the unpalatable truth is that there are limits to public health funding and elective surgery is the easiest for funders to ration. Explicit rationing is likely to become increasingly common in other public health systems. We have continued to lobby for improved access but are obliged to prioritize patients.

The NZOA score does appear to be an effective scoring tool. Its purpose is to ration access to hip and knee arthroplasty rather than determine whether surgery is indicated. The threshold in place at any institution is not fixed but will depend on the balance of supply and demand. In our institution, it would be rare to contemplate surgery in a patient who scored less than 50 points (10 of 608 in this series). The tool appears to be successful at distinguishing between patients below 70 points and those with higher scores with respect to severity of symptoms from patient-reported scores. The problem is around the threshold of 70. If our threshold had dropped to 70 points, the number qualifying for surgery without the use of clinical over-ride would have increased by 50% from 324 to 494. This limits its effectiveness as a discriminatory tool. Similar bottlenecks may occur at other scores depending on the threshold in place in any hospital (scores of 79, 66, and 62 are commonly seen). Using a single nurse to score all patients has removed some of the variability inherent in a subjective scoring system. Before this, there were legitimate concerns about the consistency of scoring. Meaningful comparison of access thresholds across the country needs the use of validated patient-derived scores in addition to the NZOA tool.

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ON BEHALF OF THE MOA TRIAL TEAM

The ShortMAC: Minimum Important Change of a Reduced Version of the Western Ontario and McMaster Universities Osteoarthritis Index

Perceived respondent burden, data completeness, and response rate are important considerations when designing outcome measure instruments for research and selecting appropriate questionnaires for use in clinical practice. Respondent burden may be reduced by reducing questionnaire length (and therefore the time required to complete the questionnaire) through avoiding redundancies; ensuring the questions are relevant to the patient's condition, sex, and culture; and keeping instructions clear and concise.[20,25,29]

STUDY DESIGN: Clinical measurement study; secondary analysis of randomized clinical trial data.

BACKGROUND: A 12-item shortened version (ShortMAC) of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), a condition-specific, patient-reported osteoarthritis index, has been derived, published, and validated. The minimum important change (MIC) of the ShortMAC has not been reported or compared with the traditional 24-item WOMAC.

OBJECTIVES: To investigate the MIC of the 12-item ShortMAC and the traditional 24-item WOMAC across 3 levels of patient-perceived global change.

METHODS: The Management of OsteoArthritis Trial cohort of 206 consecutive patients with knee or hip osteoarthritis was assessed at the initial visit and after 9 weeks of physical therapy (n = 155) or usual medical care (n = 51). The global rating of change instrument, assessed at the 9-week visit, provided the anchor. The MIC was calculated using receiver operating characteristic curve methodology for the ShortMAC and the traditional WOMAC, across 3 levels of patient-perceived change (small, medium, and large change) defined by the global rating of change.

RESULTS: The MICs for the ShortMAC and traditional WOMAC (both transformed to a scale from 0 to 100) were 7.9 and 9.8 points for small change, 8.4 and 9.8 points for medium change, and 12.1 and 10.1 points for large change, respectively. The MICs of the pain and function subscales are also reported for small, medium, and large changes.

CONCLUSION: The lower point estimates for the MIC of the ShortMAC compared with that of the traditional WOMAC, using conventional definitions of MIC and half the number of items, indicate greater efficiency for use in clinical trials and reduced patient burden. *J Orthop Sports Phys Ther 2018;48(2):81-86. Epub 21 Oct 2017. doi:10.2519/jospt.2018.7676*

KEY WORDS: *minimum clinically important difference, minimum important difference, osteoarthritis, responsiveness*

The most widely accepted condition-specific patient-reported outcome instrument for assessing pain and physical function in people with osteoarthritis (OA) of the lower limbs is the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).[6,8] The WOMAC consists of 24 questions that measure pain (5 items), stiffness (2 items), and function (17 items) (**TABLE 1**). Whitehouse et al[29] recognized the necessity and benefits of shortening the WOMAC[10,22] and proposed an abridged version of the WOMAC. The resulting reduced WOMAC kept the WOMAC pain subscale (WOMAC-P) unchanged, eliminated the 2-item WOMAC stiffness subscale, and removed 10 items from the WOMAC physical function subscale (WOMAC-F) that were found to be differentially applicable to sex or cultural groups, redundant in the same construct (eg, eliminating 1 of 2 stair items), open to misinterpretation, a poor model fit, or associated with a high proportion of missing responses (**TABLE 1**).[10,22] Whitehouse et al[29] demonstrated the reliability, validity, and responsiveness (in terms of standardized response means) of the reduced WOMAC-F in a clinical cohort of patients with hip or knee OA undergoing total joint replacement surgery. Subsequently, Yang and

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colleagues[32] validated the internal consistency, reliability, and responsiveness of the reduced WOMAC-F in a nonsurgical cohort, thus showing its generalizability beyond patients undergoing total joint replacement, and recommended its use during nonsurgical interventions.

In clinical practice and research, it is crucial to be able to interpret the meaningfulness of change in the score of an outcome measure over time.[15] The most important clinimetric property for interpreting responsiveness to change is the minimum important change (MIC). The MIC of the shortened version of the Western Ontario and McMaster Universities Osteoarthritis Index (ShortMAC) or its subscales has not been reported. The aim of this study was, therefore, to investigate the MIC of the ShortMAC (7-item reduced WOMAC-F plus 5-item WOMAC-P: a 12-item questionnaire) alongside the full, traditional version (24-item questionnaire) across 3 levels of patient-perceived importance.

METHODS

A total of 206 patients from the Management of OsteoArthritis (MOA) Trial, a randomized controlled trial of nonsurgical interventions in patients with hip or knee OA, were evaluated at recruitment and again after 9 weeks of physical therapy interventions (n = 155) or usual medical care (n = 51).[1] Participating patients were referred to the trial by their general practitioner, or referred by their general practitioner to the Department of Orthopaedic Surgery (Outpatient Clinic, Dunedin Public Hospital, New Zealand) for an orthopaedic outpatient consultation, but did not meet the priority criteria to be waitlisted for hip or knee joint replacement surgery. Inclusion in this study required participants to meet the clinical criteria of knee or hip OA diagnosis as outlined by the American College of Rheumatology.[3,4] People with previous surgical intervention, recent analgesic initiation, and physical or mental impairment that would prevent participation were excluded, as previously described.[1]

TABLE 1 Items Included in the Traditional WOMAC and ShortMAC Instruments

Dimension Assessed/Item	Traditional WOMAC	ShortMAC
Pain		
1. While walking on a flat surface	X	X
2. Ascending or descending stairs	X	X
3. At night while in bed	X	X
4. Sitting or lying	X	X
5. Standing upright	X	X
Stiffness		
1. On first waking in the morning	X	
2. Later in the day	X	
Function		
1. Descending stairs	X	
2. Ascending stairs	X	X
3. Rising from sitting	X	X
4. Standing	X	
5. Bending to floor	X	
6. Walking on flat surface	X	X
7. Getting in/out of car	X	X
8. Going shopping	X	
9. Putting on socks	X	X
10. Rising from bed	X	X
11. Taking off socks	X	
12. Lying in bed	X	
13. Getting in/out of bed	X	
14. Sitting	X	X
15. Getting on/off the toilet	X	
16. Heavy domestic duties	X	
17. Light domestic duties	X	
Total number of items	24	12
Instrument range*	0-240	0-120

Abbreviations: ShortMAC, shortened version of the Western Ontario and McMaster Universities Osteoarthritis Index; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.
**A higher score indicates greater symptoms/limitations.*

All of the participants completed questionnaires, including the traditional 24-item WOMAC (0-240 scale), at their initial assessment and again after 9 weeks of therapy or usual care. To aid in comparisons across studies, we report WOMAC scores both on the original scale and normalized to a 0-to-100 scale. At the 9-week assessment, participants also completed the 15-point global rating of functional change (GROC) instrument.[16] Global change instruments are the recommended reference anchor for MIC studies.[2,16,27]

Three levels of change on the external anchor, the GROC instrument, were defined, as previously described.[2] These levels represented small, medium, or large patient-perceived change. The MICs were calculated for the traditional WOMAC and the ShortMAC, as well as for subscales (the WOMAC-P, the full WOMAC-F, and the reduced WOMAC-F), across the 3 levels of change, using receiver operating characteristic curve methodology,[11] and cross-checked with the sum-of-squares method

using the Youden approach, wherein sensitivity and specificity are equally weighted.[13,14] Using the GROC as the reference standard for change,[11] responsiveness was assessed first by using the area under the curve (AUC) to assess the ability of the scale to differentiate those patients who improved from those who did not[11] and, second, by assessing correlation with the GROC.[11] An AUC above 0.70[11] and a correlation of 0.50 or greater were considered acceptable responsiveness,[11] and a difference of 0.10 was considered significant.[11] Standard error of measurement (SEM) was calculated, and minimum detectable change (MDC) was defined at the 90% confidence level (MDC_{90}) as $SD_{change} \times 1.645$, where SD_{change} is change in score in the group defined as no change (ie, GROC scores of 6 to 10) and 1.645 is the z-score for 2-sided 90% confidence limits.[11] In addition, internal consistency was assessed through calculation of Cronbach's alpha. We considered a coefficient over .7 acceptable and hypothesized reduced Cronbach's alpha in the ShortMAC, toward a desired upper limit of .95,[26] as evidence of reduced redundancy among instrument items.[27,29,32] The floor and ceiling effects were also investigated, where a maximum of 15% of participants reporting the worst or best possible score, respectively, across the instrument of interest was deemed acceptable.[17] Calculations were performed using IBM SPSS Statistics Version 24.0 (IBM Corporation, Armonk, NY).

TABLE 2 Characteristics of Participants and Description of Data at Initial and Final Visits*

	Baseline	At 9 Weeks
Age (n = 206), y	66.6 ± 9.5	
Sex, n (%)		
Male	92 (44.7)	
Female	114 (55.3)	
Traditional WOMAC (0-240)	101.00 ± 54.21 (2-223)	82.53 ± 54.30 (2-206)
Cronbach alpha†	.974	.977
ShortMAC (0-120)	50.02 ± 27.54 (1-110)	40.51 ± 27.31 (0-108)
Cronbach alpha†	.954	.955
GROC (1-15)	NA	
Large change (13+)	…	50
Medium change (12+)	…	66
Small change (11+)	…	87
No change (6-10)	…	86
Worse (1-5)	…	33
Correlations with GROC	NA	
Traditional WOMAC	…	0.59‡
ShortMAC	…	0.57‡
WOMAC-P subscale	…	0.53‡
Traditional WOMAC-F	…	0.57‡
ShortMAC-F subscale	…	0.55‡

Abbreviations: F, function; GROC, global rating of change; NA, not applicable; P, pain; ShortMAC, shortened version of the Western Ontario and McMaster Universities Osteoarthritis Index; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.
**Values are mean ± SD or mean ± SD (range) unless otherwise indicated.*
†Cronbach alpha is an indicator of internal consistency.
‡P<.001.

RESULTS

The baseline characteristics of the 206 recruited participants are presented in **TABLE 2**, along with the self-reported scores from the 24-item WOMAC questionnaire and the 12-item reduced form at the initial and 9-week visits, the Cronbach alpha for each time point, numbers at each analysis level of the GROC, and correlations with the GROC at 9-week follow-up.

TABLE 3 reports the SEM, MDC_{90}, MIC, and AUC results. The point estimate of the MIC for the ShortMAC was lower than that for the traditional WOMAC at small and medium, but not large, levels of change; however, responsiveness did not significantly differ by AUC or correlation (**TABLES 2** and **3**). The lower bound of the 95% confidence interval of the AUC exceeded 0.70 for all scales and subscales at each level investigated. **TABLE 4** reports the proportion of minimum score (floor) or maximum score (ceiling) totals reported for the full WOMAC and ShortMAC. There was no evidence of significant floor or ceiling effects at either time point across the instruments, or at total scale or subscale levels.

DISCUSSION

With the increased prominence of patient-reported outcomes in clinical practice and research, interpreting the meaning of outcome measure change is essential. To our knowledge, this is the first study to report the MIC for both the traditional WOMAC and a reduced-item form of the WOMAC instrument. Within this same sample of patients with a wide spectrum of hip or knee OA, receiving physical therapy interventions or usual medical care, we have shown that the ShortMAC was similarly responsive to change. While the ShortMAC has a lower point estimate for the MIC compared with that of the traditional WOMAC at the small and medium levels, responsiveness was not significantly different in any analysis. The ShortMAC's fewer number of items and slightly lower MIC have favorable implications both for the efficiency of questionnaire administration and for the efficiency of sample-size requirements for clinical trials.

TABLE 3 MIC and AUC for the Traditional and Reduced WOMAC Instruments and Subscales

Outcome Measure	No Change (n = 86)	Small Change (GROC 11+) (n = 87)* MIC†	MIC‡	AUC§	Medium Change (GROC 12+) (n = 66)* MIC†	MIC‡	AUC§	Large Change (GROC 13+) (n = 50)* MIC†	MIC‡	AUC§
Traditional WOMAC (0-240)		23.5	9.8	0.802 (0.738, 0.865)	23.5	9.8	0.822 (0.756, 0.888)	24.125	10.1	0.838 (0.774, 0.901)
SEM	7.6									
SDC_{90}	17.7									
ShortMAC (0-120)		9.5	7.9	0.788 (0.724, 0.851)	10.125	8.4	0.819 (0.754, 0.885)	14.5	12.1	0.835 (0.769, 0.902)
SEM	7.6									
SDC_{90}	17.7									
WOMAC-P subscale (0-50)		2.5	5.0	0.779 (0.715, 0.843)	4.5	9.0	0.814 (0.751, 0.877)	5.5	11.0	0.808 (0.736, 0.880)
SEM	9.7									
SDC_{90}	22.6									
WOMAC-F subscale (0-170)		5.5	3.2	0.798 (0.732, 0.863)	5.5	3.2	0.826 (0.759, 0.894)	5.5	3.2	0.840 (0.776, 0.903)
SEM	8.0									
SDC_{90}	18.6									
ShortMAC-F subscale (0-70)		6.5	9.3	0.774 (0.708, 0.841)	5.5	7.9	0.806 (0.736, 0.877)	8.5	12.1	0.831 (0.764, 0.899)
SEM	7.6									
SDC_{90}	17.7									

Abbreviations: AUC, area under the receiver operating characteristic curve; F, function; GROC, global rating of change; MIC, minimum important change; P, pain; SDC_{90}, smallest detectable change at upper bound of 90% confidence limits; SEM, standard error of measurement; ShortMAC, shortened version of the Western Ontario and McMaster Universities Osteoarthritis Index; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.
**Small, greater than or equal to "somewhat better" on the GROC; medium, greater than or equal to "moderately better" on the GROC; large, greater than or equal to "quite a bit better" on the GROC, as rated by participants.*
†Original scale.
‡Transformed scale (0-100).
§Values in parentheses are 95% confidence interval.

TABLE 4 Floor and Ceiling Effects of the Traditional and Reduced WOMAC Instruments and Subscales

Outcome Measure	Relevant Measure	Baseline Floor Effect (Worst Outcome)	Baseline Ceiling Effect (Best Outcome)	9 Weeks Floor Effect (Worst Outcome)	9 Weeks Ceiling Effect (Best Outcome)
Traditional WOMAC (0-240)	Traditional WOMAC	0%	0%	0%	0%
ShortMAC (0-120)	ShortMAC	0%	0%	0%	1/206, 0.5%
Subscales					
WOMAC-P subscale (0-50)	Traditional WOMAC, ShortMAC	0%	2/206, 1%	0%	6/206, 2.9%
WOMAC-S subscale (0-20)	Traditional WOMAC	1/206, 0.5%	8/206, 3.9%	1/206, 0.5%	11/206, 5.3%
WOMAC-F subscale (0-170)	Traditional WOMAC	0%	2/206, 1%	0%	1/206, 0.5%
ShortMAC-F subscale (0-70)	ShortMAC	0%	4/206, 1.9%	0%	4/206, 1.9%

Abbreviations: F, function; P, pain; S, stiffness; ShortMAC, shortened version of the Western Ontario and McMaster Universities Osteoarthritis Index; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

The baseline WOMAC values and the extent of change are consistent with those reported previously in studies looking at nonsurgical treatment of OA of the lower extremity,[5,30,32] supporting the external validity of our MIC estimates. Williams et al[30] reported the MIC for the WOMAC at 2 months to be 4.0 (0-100 scale) using the Youden index to identify the MIC estimate (sensitivity and specificity equally weighted), or 8.8 when using a specificity value of 0.80. Those MIC values, and those found in the current study, are lower than the 14 to 22 points reported by Escobar et al[12] (0-100 scale) in individuals undergoing

total joint replacement and, therefore, in whom larger changes would be expected. They also used a different anchor question with larger steps.

The MICs corresponding to small, medium, and large self-perceived changes were remarkably stable for both instruments. The ShortMAC demonstrated appropriate stepwise increases in the MIC for increasing levels of the GROC, which were less evident for the full WOMAC version. This is likely due to reduced item redundancy and can be interpreted as evidence of greater sensitivity to change of the ShortMAC. Because we used a 15-point scale in the GROC, the numbers of respondents per scale point were relatively small (eg, only 12 of 206 participants reported feeling "moderately better"); however, categorizing the GROC responses into 3 levels of change ensured sufficient numbers at each level (**TABLE 2**), giving us the ability to show the extent of MIC improvement across levels of patient-perceived change.

One of the limitations of this research that must be considered is the anchor used in the present study, the GROC instrument, which asked participants to compare the current impact of OA on their overall health status to its impact 9 weeks earlier and at baseline. Although the GROC has been shown to reflect a bias toward current status rather than equally weighting both current and baseline components of "change,"[18,23,24] it is still the recommended reference anchor for MIC studies.[2,11,16,27] Also, it captures more domains of health status than merely pain and physical function, so it does not correlate exactly with the WOMAC. Also, as with any self-reported questionnaire, the GROC is limited by the accuracy of patients' recall, so it is not recommended for use in clinical practice or for other applications with differing periods of recall.[23,24] In this study, the recall time was consistent between the 2 instruments, and a 9-week recall period is short enough to not be considered problematic.[26] The MIC estimates were lower than the MDC_{90}, limiting the interpretation of the MIC for individual patients.[11] However, the test-retest scores used to calculate the SEM and MDC_{90} were conducted 9 weeks apart and, while ideal for estimating the MIC, were likely to bias MDC upward. Other sources recommend SEM or $0.5 \times SD_{change}$ as another way to estimate real change over measurement variability, the latter of which, in this case, would be 5.4 to 6.9 points.[11,15] Finding the true MDC would require further research specifically assessing test-retest reliability of the instruments in unchanged participants.

As noted previously,[29,32] Cronbach's alpha was particularly high in the traditional WOMAC, highlighting the apparent redundancy present in the instrument. Reducing the questionnaire decreased this value toward the desired upper limit of .95,[26] thereby producing more favorable internal consistency, but to a lesser extent than had been previously reported.[29,32] A ceiling effect in the traditional WOMAC has been reported following surgical intervention.[9,12,19,21] In the current study, where nonsurgical intervention was applied, the traditional and reduced-form WOMAC instruments and subscales demonstrated an absence of any floor effects, and minimal ceiling effects well within acceptable levels. This is consistent with earlier research, Yang et al[32] also having reported minimal overall floor and ceiling effects after "conservative" treatment.

The patients included in the current study were involved in a trial of nonoperative therapy for OA of the lower limb. While the type of therapy and its efficacy are of little relevance to the objectives of the current study, at the time of recruitment, these participants were deemed to have a wide spectrum of symptom severity, from mild to significantly impaired by OA, but were not on the waiting list for total joint replacement surgery. As such, their disease burden would be expected to cover a broader range but average less than that of patients referred for surgery, and their treatment effects to be less marked than those in patients scheduled for total joint replacement. Both the traditional WOMAC and the ShortMAC have the sensitivity to detect change with nonoperative therapy, thereby expanding their applicability beyond surgical intervention studies.[29,32]

Also with regard to generalizability, to aid in comparisons across studies, we reported both the raw scores and results normalized to a 0-to-100 scale. The traditional WOMAC instrument is available in 3 formats: 5-point Likert scale (range, 0-96), 100-mm visual analog scale (range, 0-240), and, as in the current study, 11-point numeric rating scale (range, 0-240).[7] While no systematic differences have been reported between the scales, given these modifications and others adopted in the literature, it is essential that the scale and the score range be clearly defined.[31]

Other studies have proposed short-form versions of the WOMAC, including reducing the number of items in the WOMAC-P subscale, but no consensus has been reached.[10,22,28] This ShortMAC, a reduced version of the WOMAC, is the only reduced version to have been independently tested in both surgical and nonsurgical patient populations, and for which MIC estimates are available.[29,32]

CONCLUSION

The results of this study support recommendation of the reduced-form WOMAC as a patient-friendly alternative to the traditional WOMAC instrument to assess the impact of OA on a patient's daily life, and as a valid and responsive means of assessing change in status following surgical or nonsurgical intervention.

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APPENDIX

THE MOA TRIAL TEAM

Name	Role on Trial Team	Contribution	Affiliation
Professor J. Haxby Abbott	Principal investigator	Conception, design, protocols, coordination, monitoring, analysis, interpretation, reporting	University of Otago
Professor A. John Campbell (deceased)	Coinvestigator, consultant geriatrician	Design, coordination, interpretation	University of Otago
Associate Professor M. Clare Robertson (retired)	Coinvestigator	Economic evaluation, design, protocols, coordination, monitoring, interpretation	University of Otago
Professor G. David Baxter	Coinvestigator	Coordination, monitoring	University of Otago
Professor Jean-Claude Theis	Coinvestigator, consultant orthopaedic surgeon	Coordination, monitoring, recruitment	University of Otago
Professor Paul Hansen	Health economist	Design and interpretation	University of Otago
Dr Joanne E. McKenzie	Statistician	Protocol design	University of Otago Monash University
Debra McNamara	Research nurse	Participant recruitment and screening	University of Otago
Dr Catherine Chapple	Outcome assessor	Design of intervention protocols	University of Otago
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Name	Contribution	Affiliation
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Professor Jeffrey Basford	Research advisor, design	Mayo Clinic
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National Referral Prioritization tool for first specialist assessment: results of a pilot study in orthopaedic surgery

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Abstract

Background: Most public hospitals are receiving more referrals for first specialist assessment than they have capacity to see. Traditional priority categories are too broad for effective discrimination. In New Zealand (NZ) explicit prioritization is required by legislation and supported by the Medical Council of NZ. A new generic National Referral Prioritization tool (NRPT) has been developed which includes a patient impact on life score. This study reports its trial implementation in orthopaedic surgery in a single centre.

Methods: Four months of referrals to the orthopaedic department were prioritized using the new NRPT and traditional clinical priority categories. Scores and acceptances were compared across conditions, surgeons and against the traditional categories.

Results: The mean NRPT was 60.1 (range 23–99). The correlation with impact on life was 0.59. There was good consistency of scores between surgeons. The NRPT score was significantly different across clinical priority categories (urgent, semi-urgent, routine). A total of 305 referrals (49%) were accepted using the NRPT compared with 493 (79%) if the traditional tool had been used. Patients with foot and ankle, carpal tunnel syndrome and upper limb conditions had the lowest scores and were more likely to be declined.

Conclusions: The NRPT is the first tool designed to prioritize referral letters. It is more discriminating than the clinical priority categories used previously. It allows fine-tuning of a threshold score to balance acceptances and capacity.

Introduction

There is increasing demand for first specialist assessment (FSA) and elective orthopaedic surgery. In New Zealand (NZ), a patient must be seen within 4 months of referral by their general practitioner (GP) as legislated in the National Waiting Time Policy (1999) and subsequent review by the Office of the Auditor General (2011).[1] If the District Health Board (DHB) does not have the capacity to see a patient within this time period they can be declined and returned to the GP with some form of management plan. Similarly, if a patient is offered surgery, then it must be performed within 4 months of the certainty decision.[1] This has resulted in the need for triage, prioritization and varying degrees of rationing.

Triage is defined as ordering a queue based on urgency while prioritization is the ordering of a queue by multiple criteria. Rationing occurs when capacity is limited and can be applied to a queue, however, ordered. Explicit prioritization is required under the legislation and is supported by the Health and Disability Commissioner and the Medical Council of New Zealand.[2] This has led to the development of various scoring tools for the prioritization of patients for surgical treatment.[3–7] However, to date, we are unaware of any scoring systems that have been used to prioritize requests for FSA. Triage categories, such as urgent, semi-urgent and routine lack discrimination when demand exceeds capacity.[8,9] Condition-specific scores such as the Oxford hip or knee score or Western Ontario MacMaster Osteoarthritis index have been used to set thresholds for referral for total hip or knee replacement despite not being designed for that purpose.[10,11] A systematic review has highlighted the need for the use of standardized tools and procedures for triage.[12]

The National Referral Prioritization tool (NRPT) is a generic tool designed to be used across both surgical and non-surgical specialities. It is similar to the surgical prioritization tools used in

orthopaedic and general surgery and includes a patient impact on life (IOL) score.[7,13] It assesses the severity of symptoms, risk and impact of deterioration, and ability to benefit from a specialist appointment.

It was decided that the new NRPT should be piloted in our department as part of a recovery programme to reduce the number of patients waiting more than 4 months for their FSA as required by Ministry of Health guidelines.[1]

The purpose of this study is to report on the implementation and results of the pilot trial of the NRPT in orthopaedic surgery in our hospital.

Development and design

The NRPT includes a patient IOL score based on six questions scored by the patient on a scale of 1–6 points (Document S1). The surgeon completes five questions on the severity of symptoms, the functional impact of the condition, the likelihood of deterioration within 6 months, the consequence of deterioration and factors that may affect the ability of the patient to benefit (Document S2). The weighting of these questions was developed using the PAPRIKA methodology and the 1000minds software where clinicians are asked to make multiple pair-wise rankings of alternatives.[14,15] This resulted in weightings of: 23.1% consequence of deterioration; 20.5% clinician derived symptom severity; 17.9% clinician function severity; 12.8% for each of Patient IOL, risk of deterioration and other factors. After completing all questions on the web-based system, a priority score is automatically generated out of a maximum 100 points (Document S3). The determination of the threshold score for access is a joint management and clinician decision based on the capacity of a service and forecast demand.

If the score is below the threshold set by the DHB a patient can be given a clinical override if special factors exist that are not captured by the tool. There is an option for automatic priority for special cases such as a patient with malignancy or a sub-acute presentation with a high likelihood of catastrophic consequences. There is no reference in the tool for inability to work because in NZ being in paid employment cannot be ethically used to discriminate.

Methods

Prior to the introduction of the prioritization tool all referrals to the orthopaedic department were triaged by consultant orthopaedic surgeons based on their area of sub-specialization using the categories – Immediate, Urgent, Semi-urgent, Routine and Low Priority. Patients with hip or knee osteoarthritis could also be triaged to the Joint Clinic (JC), a physiotherapist- and nurse-led clinic, for non-operative treatment.[16,17] Approximately, 30% of referrals were declined, which included most routine and low priority patients.[16] Referrals with a triage category of semi-urgent and above were usually accepted. However, there was no mechanism to match acceptances with future capacity.

All GP referral letters received in the first 4 months of the trial (May to August 2019) were triaged using the traditional tool and scored with the new prioritization tool. The surgeons had access to the GP letter, the patient IOL score, all relevant investigations and hospital electronic records to help inform the scoring. Referrals for paediatric conditions and acute referrals better seen in Fracture Clinic were excluded. Patient IOL scores were collected by mail, email or phone by an administration clerk during the pilot period. The threshold score was adjusted weekly based on the predicted capacity of the service. During this phase, surgeons were blinded to the final acceptance/decline decision but could use clinical override if they felt it justified based on the final score.

Statistical analysis was performed using R v3.5.1 (R-Foundation, Vienna, Austria, http://www.R-project.org/) and included comparison of patient IOL scores and total score using correlation coefficients. Means and standard deviations were calculated to describe the distribution of scores for each condition. Scores were compared across conditions and across the traditional clinical priority categories using pairwise *t*-tests. Consistency between surgeons was analysed by pairwise t-tests, within conditions to allow for variations in symptoms and scoring across conditions. All pairwise *t*-tests were adjusted for multiple comparisons using the methods of Holm.[18]

Ethics approval was given by University of Otago Ethics Committee (Health) HD19/043.

Results

A total of 673 referrals were received of which 45 (6.7%) were returned due to missing information (e.g. recent X-ray, height and weight, neurophysiological studies). Of the remaining 628 referrals, three were triaged as special case with automatic priority. Details of referrals by condition are given in Table 1. The NRPT returned scores ranging from 23 to 99 out of 100. No banding or clustering was observed and the distribution of the scores had a relatively normal distribution (Fig. 1). The patient IOL score ranged from the minimum of 6 with significant clustering only at the maximum score of 36. (Fig. 1) There was reasonably strong correlation between the NRTP score and the patient IOL score ($r = 0.59$).

There was generally good consistency between the 11 surgeons with one surgeon scoring consistently lower for most conditions. One of three spine surgeons scored significantly lower but was only involved in scoring for the first 2 months of the project.

The mean scores were highest for patients with hip, spine and shoulder conditions and lowest for carpal tunnel syndrome (CTS), foot and ankle and upper limb problems. (Table 1). The NRPT score generally mirrored the patient IOL score, but spine conditions and CTS were scored more highly by clinicians than patients relative to the other conditions (Fig. S1). The distribution of scores by condition for acceptances and declines are shown in Figure 2.

The mean NRPT score increased by only 4 points to 65 over the 17 weeks (0.3 points per week, 95% confidence interval 0.06–0.53, $P = 0.012$). The threshold score increased for the first 13 weeks from 52 points in week 1 and has stabilized at 71 points. There was increasing use of clinical override from Week 13 onward.

There were statistically significant differences between the average NRPT scores for the traditional clinical priority categories ($P < 0.0001$) (Fig. S2). The difference in scores between patients accepted and declined with the NRPT for semi-urgent ($P < 0.0001$)

Table 1 National Referral Prioritization tool and patient impact scores, by condition with proportions accepted, over-ridden and declined

Condition	*n*	Prioritization tool score (range)	Patient impact on life score (range)	Accept, *n* (%)	Override, *n* (%)	Decline, *n* (%)
Hip	109	68.2 (13.5) (24–99)	28.8 (6.8) (9–36)	66 (60.6)	4 (3.7)	39 (35.8)
Spine	129	66.2 (13.1) (33–89)	24.4 (8.6) (6–36)	68 (52.7)	3 (2.3)	58 (45.0)
Shoulder	43	66.0 (10.3) (48–83)	27.2 (7.9) (8–36)	20 (46.5)	0 (0.0)	23 (53.5)
Dupuytrens	16	65.4 (11.0) (48–83)	25.6 (8.3) (9–36)	7 (43.8)	1 (6.2)	8 (50.0)
Knee	138	62.6 (11.3) (29–84)	27.3 (6.4) (7–36)	62 (44.9)	8 (5.8)	68 (49.3)
Carpal tunnel (CTS)	57	60.1 (11.7) (26–82)	21.3 (8.3) (6–36)	19 (33.3)	8 (14)	30 (52.6)
Foot/ankle	80	59.3 (12.2) (23–88)	23.2 (7.5) (6–36)	29 (36.2)	3 (3.8)	48 (60.0)
Upper limb	44	56.1 (15.2) (27–89)	23.0 (9.0) (6–36)	11 (25.0)	4 (9.1)	29 (65.9)
Other	12	53.2 (14.3) (23–68)	21.0 (9.8) (6–36)	2 (16.7)	1 (8.3)	9 (75.0)
Total	628	63.3 (13.0) (23–99)	25.3 (8.2)(6–36)	284 (45.2)	32 (5.1)	312 (49.7)

The following were statistically significant differences ($P < 0.05$): National Referral Prioritization score: hip > knee, CTS, foot and ankle, other. Spine > foot and ankle, upper limb, other. Shoulder > upper limb, other. Patient impact on life score: hip > spine, foot and ankle, upper limb, CTS, other. Knee > foot and ankle, upper limb, CTS. Shoulder > CTS.

and routine ($P < 0.003$) was also significant. Under the old system 493 patients would have been accepted for an FSA (79% of referrals). With the NRPT, 305 (49%) patients were accepted including 33 with clinical override (5.3% of all referrals).

Discussion

While many systems have been used to prioritize patients for surgery this is the first tool we are aware of that has been used to prioritize GP referral letters. The NRPT gives a wide range of scores and is more discriminating than the traditional triage categories. There is good correlation between the patient IOL score and the NRPT score and good consistency between clinicians. The NRPT meets its goal of being a fair and consistent method of prioritizing referrals and allows fine-tuning of an access threshold to match acceptances with capacity. The main disadvantage of the tool is that it is time consuming with delays in triaging referrals and some resistance from surgeons.

A feature of the tool is that it includes a patient IOL score that has been validated when used in the orthopaedic surgical prioritization tool.[7] In this study it correlated reasonably well with the total score, unlike in the General Surgery pilot study.[13] This may be because of clinicians giving higher scores for the 'likelihood of deterioration' and 'consequences of delay' questions in General Surgery, as we saw for CTS and spine conditions. An administration assistant collected the patient IOL during the study. In future it is hoped that the patient IOL scores will be collected and included in an electronic referral.

In our hospital, the goal of DHB management was to reduce the number of referral acceptances to 50% in order to improve compliance with Ministry of Health performance indicators. This required an improved prioritization system. The surgeons agreed to pilot the NRPT on condition that it was formally evaluated. The threshold score was set by the DHB to reflect this need for rationing. Explicit prioritization and associated rationing, while distasteful to surgeons, is part of the NZ public health care system and required by legislation. The Medical Council of New Zealand allows clinicians to advocate for patients but they have a duty to responsibly use resources and must be a party to any rationing decisions.[2]

During this pilot we saw minimal score creep and low use of clinical override. However it is likely that surgeon behaviour will change leading to further creep, gaming and increased use of override as the threshold becomes widely known. All scoring systems while initially effective tend to fail if the balance between demand and capacity is too unequal.[6,19,20]

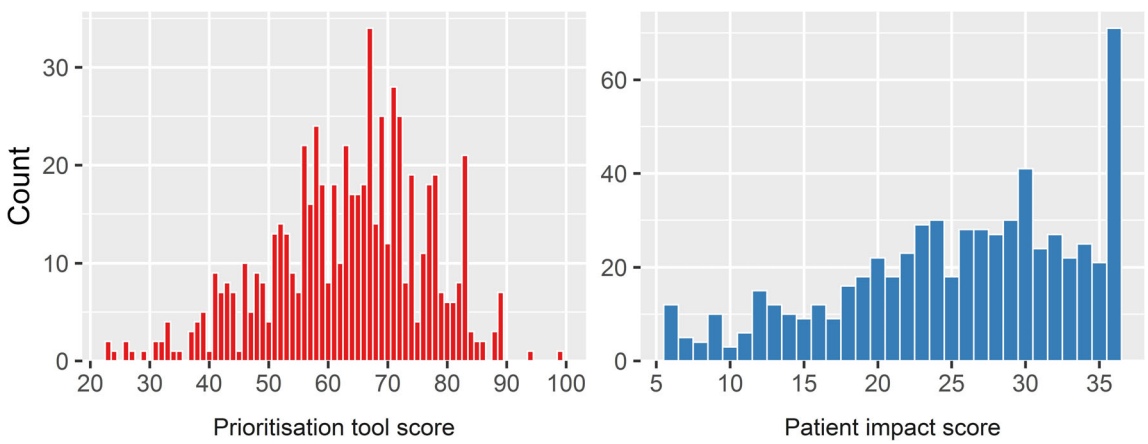

Fig 1. Distribution of scores: National Referral Prioritization tool and patient impact on life score.

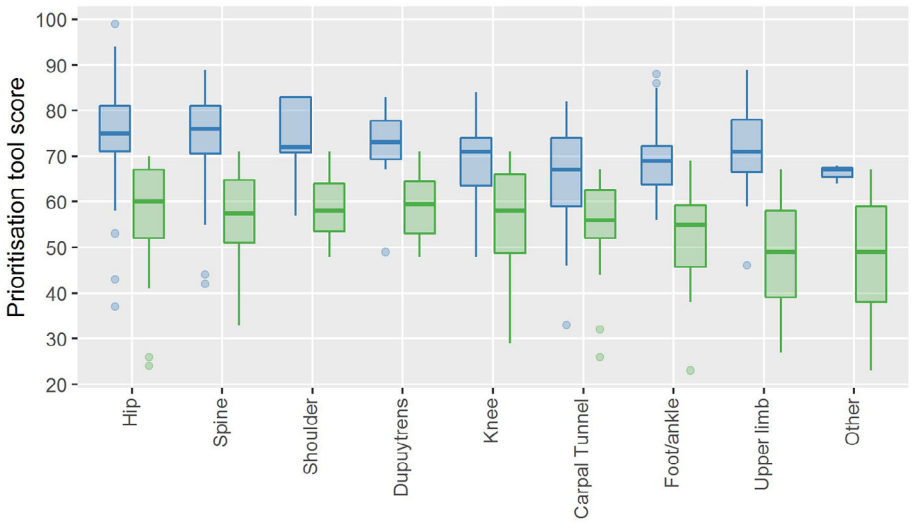

Fig 2. Distribution of National Referral Prioritization tool scores for acceptances and declines for first specialist assessment, by condition. ( ), Accepted; ( ), declined.

In New Zealand there have been a number of different approaches to managing referrals. Canterbury DHB introduced Health Pathways which include guidelines to GPs on when to refer patients to avoid inappropriate referrals.[21] Inglis *et al*. reported using two experienced surgeons to triage all referrals with hip and knee problems, which effectively became a virtual FSA.[8] 50% of referrals were declined but 97% patients who were seen were given certainty for surgery.[8] A similar system was used for spine referrals.[9] While this is efficient and effective we do not believe it is true prioritization. In contrast we have focused on surgical prioritization using a standardized tool after a patient has been assessed in person resulting in 32% of patients being declined total hip or knee replacement due to inadequate surgical capacity.[6,20]

In other health-care systems, it may not be permissible to decline referrals and many use some form of triaging or alternate care pathways, summarized in two recent systematic reviews.[12,22] A common strategy uses non-medical staff such as extended scope physiotherapists to triage referrals using standardized protocols and to see patients in multidisciplinary clinics.[12] We have used this successfully for patients with hip and knee OA with the Joint Clinic.[16] While designed to maximize non-operative treatment it also worked well as a triage tool ensuring appropriate patients in need of surgery were seen by orthopaedic surgeons.[17]

The person triaging is dependent on the information given in the referral letter. This is important in specialities where patients may have a serious underlying condition or malignancy. Scoring tools have been developed to improve and assess the quality of referrals.[23] In this study only 6.7% referrals were returned prior to scoring due to missing information. Access to electronic records and X-ray systems helped to fill any gaps.

The NRPT allows for automatic priority if there is a high suspicion of cancer or likelihood of catastrophic consequences but was only used in three cases (0.5%) in this study. Automatic priority can and should be used more frequently in other specialities to avoid the risk of missing a malignancy or similar. The NRPT can prioritize the remaining patients with benign conditions if capacity to see these patients is limited.

Strength of this study is that the NRPT was used to prioritize all orthopaedic referrals during the 4 month study period. A patient IOL score was used and correlated well with the total score. The surgeons were familiar with triaging and the use of the national orthopaedic surgical prioritization tool. A limitation is that the threshold score varied during the pilot period, which meant that some patients may have qualified 1 week but not the next. However the threshold stabilized as anticipated after 3 months. We did not sub divide sub-speciality areas into specific diagnosis because the groups would become too small. We have only included orthopaedic referrals so cannot assess whether the NRPT is generalisable across other specialties.

Conclusion

The NRPT is the first tool designed specifically to prioritize referral letters. It generates a wide range of possible scores and avoids clustering and so provides advantages over triaging using clinical priority. In orthopaedics, some conditions may have a low mean score but the most severely affected of patients with those conditions will still be accepted.

The tool was designed for the NZ system where there is a requirement for a service to see patients within 4 months of acceptance of the referral but allows a referral to be declined. It may be less applicable to other health care systems where it is expected that all referrals are seen.

An important outcome of the study has been to identify the unmet demand for orthopaedic FSA. If introduced widely, the NRPT may allow comparison of the threshold scores and demand between specialities within a DHB or between different DHBs. This may help funding decisions and resource allocation.

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Conflicts of interest

Mr Chris McEwan FRACS is employed by the NZ Ministry of Health and is Clinical Leader – Prioritisation, Electives & National Services, DHB Performance and Support and Infrastructure. He oversaw the development of the new NRPT.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Figure S1. Distribution of National Referral Prioritization tool (NRPT) score and Impact on Life score (IOL) by condition
Figure S2. National Referral Prioritization tool (NRPT) scores for acceptances and declines by clinical priority category
Document S1. Patient impact on life questionnaire
Document S2. National Referral Prioritization tool
Document S3. National Prioritization tool scoring table

Rationing of hip and knee replacement: effect on the severity of patient-reported symptoms and the demand for surgery in Otago

David Gwynne-Jones, Ella Iosua

ABSTRACT

AIM: A key Government health target has been to increase access to elective surgery. Despite this, there is a growing concern about unmet demand and increasing numbers of patients are being declined elective surgery. This study aims to determine whether there has been an increase in the severity of osteoarthritis of the hip and knee in patients undergoing publicly-funded elective total joint replacement (TJR) and any increase in demand for TJR in Otago.

METHOD: Demographic details and preoperative patient reported outcome scores (Oxford hip or knee score (OHS,OKS) and a reduced Western Ontario and McMaster Osteoarthritis Index (WOMAC) score (RWS) were collected prospectively in an historical cohort of patients undergoing total hip and knee replacement (THR, TKR) between 2006–2010. These were compared with all patients undergoing THR and TKR in the 12-month period commencing 1 November 2013, and all patients waitlisted during this period but returned to GP due to capacity issues. An estimate of current demand was made by adding all waitlisted public patients from the 12-month period to surgical numbers from private and those funded by ACC.

RESULTS: In the 2006–2010 group of 613 patients, the mean OHS was 13.6 (SD 6.7) and OKS 15.4 (SD 6.5) and RWS 30.5 (SD 8.0). Three hundred and sixty-seven patients who underwent surgery in 2013/4 had significantly poorer scores (OHS 9.9 (SD 4.9), OKS 10.6 (SD 3.8), RWS 34.8 (SD 6.7)). The scores of 194 patients returned to GP in 2013/4 were the same as the historical surgical group (OHS13.0 (SD 6.2, OKS 15.2 (SD 5.9), RWS 30.8 (SD 8.4)). Six hundred and eight patients were wait-listed for public surgery and 356 joints were performed in private or under ACC in the 12-month period. The current intervention rate in Otago is 371/100,000 per year, while the demand has risen from 417/100000 in 2010–12 to 494/100,000 per year. In 2014, the shortfall was 241 joints per year.

CONCLUSION: Patients undergoing primary elective total hip and knee replacement in Otago in 2014 are more severely disabled than between 2006–2010. Patients currently being returned to GP would have qualified for publicly funded surgery during that period. The demand for elective TJR in Otago has increased by 19% since 2012.

Hip and knee replacement are two of the most successful interventions in orthopaedic surgery. The population of New Zealand is both ageing and growing, and it is predicted that there will need to be a large increase in the numbers of joint replacements over the next 10 years.[1,2] The public health system is under significant funding constraints, and joint replacements are relatively expensive to provide. However, in the long term they are highly cost effective.[3-5] In New Zealand, the 'Joint Initiative' ran from 2004 to 2008, which led to a significant increase in the number of joint replacements performed nationally. From 2008 onwards, the funding was no longer ringfenced and was included in the orthopaedic volumes of District Health Boards (DHBs). An increase in funding for orthopaedic procedures including joint replacement was signalled in the 2015 budget.

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DHBs are required to prioritise patients and operate on the most in need. However, they are also obliged to meet Elective Surgical Performance Indicators (ESPIs). These include ESPI 5 (time to surgery from a certainty decision). This target was initially 6 months but reduced to 5 months in June 2013, and to 4 months in December 2014. This target has resulted in the so called 'financial threshold' score. If a patient is judged to benefit from surgery but capacity constraints mean that they cannot have surgery within the ESPI target, then they can be placed on Active Review if just below the threshold or returned to General Practitioner (GP).

In our district we have had significant problems with excess demand over capacity. The problems are longstanding, and in 2006 there was a well-publicised 'cull' of patients who had waited too long for surgery. Between 2010 and 2012 we estimated that the demand for elective hip and knee replacement was 41.7/10,000 per year.[6] The main drivers were the age of the population and a backlog of cases due to under-provision relative to demand.[6]

Despite using each new scoring system,[6-9] we found that the mismatch between supply and demand drove the financial threshold up in order to ensure ESPI compliance.[6] Increasingly, this is being seen in other centres in New Zealand.[10] The drive for shorter wait times for elective surgery has not been matched by any significant increase in joint replacement numbers in our region. In turn, we have noticed an increase in the severity of disease of those patients who do qualify for surgery.

In response to concerns around capacity and unmet demand, a programme funded by the National Health Board was developed to address patient flow. It was decided that all scoring for joint replacement surgery in our hospital would be by a single experienced orthopaedic nurse, the prioritisation nurse (PN), to ensure consistency and avoid accusations of surgeons 'gaming the system'.

The purpose of this study is to compare patient reported scores from a historical cohort of patients undergoing primary elective THR or TKR from 2006–2010 with patients undergoing surgery in 2013–2014, and those waitlisted but returned to GP for being below the financial threshold during the same period. A secondary goal was to determine whether the current level of demand in our local population for elective THR and TKR had increased since our previous report looking at the years 2010–2012.

Methods

In October 2013, prior to the programme commencing, the threshold for hip and knee replacement in our hospital was 80 points using the New Zealand Orthopaedic Association hip and knee prioritisation tool (NZOA score).[6] This tool was developed by the Orthopaedic Working Group of the National Waiting Times Project and introduced in 2008. There were 106 patients with certainty, 83 on active review and 181 other patients had been listed for joint replacement but returned to GP. After analysis of the waiting list figures, capacity, contracted volumes, and ESPI compliance, the financial threshold was set at 71 points commencing 1 November 2013. Active review would no longer be used and all patients falling below threshold would be returned to their GP. All patients were to be scored by the prioritisation nurse using the NZOA tool. Criteria for the use of the five components of the score, especially the consequence of delay, were agreed and policed.[11]

Data were retrieved from our department database of patients who had undergone primary hip or knee replacement (including unicompartmental knee replacement (UKR)) between 2006 and 2010. Patient details, including pre-operative scores, had been prospectively recorded in our departmental database. The patient completed a pre-operative Oxford hip or knee score (OHKS) and a reduced Western Ontario and McMaster Osteoarthritis Index (WOMAC) score (RWS). The modified Oxford score (0–48, where 0 is worst and 48 best) was used.[12] The reduced WOMAC score (RWS) uses 5 pain questions and 7 function questions (scored 0–4, where 0 is best) giving a worst score of 48.[13,14] Preoperative scores were available on 613 of 945 patients on the database.

Details of all patients undergoing elective primary total hip or knee replacement

Table 1: Comparison of demographic characteristics between 2006-10 surgery group, 2013/4 surgery group and 2013/4 return to GP group.

				2006–10 and 2013/4 comparison		2006–10 and 2013/4 Return to GP comparison		2013/4 Surgery and 2013/4 Return to GP comparison	
	2006–10 surgery	2013/4 surgery	2013/4 Return to GP	Difference (95% CI)	p	Difference (95% CI)	p	Difference (95% CI)	p
Combined	n= 613	n= 367	n=194						
Male (%)	260 (42.4)	166 (45.2)	91 (46.9)	-2.8 (-9.2, 3.6)	0.389	-4.5 (-12.5, 3.5)	0.271	-1.7 (-10.3, 7.0)	0.705
Age (SD)	69.3 (10.1)	69.3 (10.4)	67.3 (9.0)	-0.0 (-1.3, 1.3)	0.979	1.9 (0.4, 3.5)	0.016	2.0 (0.2, 3.7)	0.027
Hips	n= 355	n= 204	n=84						
Hips %	57.9	55.6	43.3	2.3 (-4.1,8.7)	0.477	14.6 (6.6,22.6)	<0.001	12.3 (3.7,20.9)	0.006
Male (%)	153 (43.1)	90 (44.1)	39 (46.4)	-1.0 (-9.6, 7.5)	0.815	-3.3 (-15.2, 8.5)	0.580	-2.3 (-15.0, 10.3)	0.720
Age (SD)	68.1 (10.8)	68.5 (10.9)	66.0 (10.6)	-0.4 (-2.3, 1.5)	0.668	2.1 (-0.5, 4.7)	0.107	2.5 (-0.2, 5.3)	0.073
Knees	n= 258	n= 163	n= 110						
Knees %	42.1	44.4	56.7						
Male (%)	107 (41.5)	76 (46.6)	52 (47.3)	-5.2 (-14.9, 4.6)	0.299	-5.8 (-16.9, 5.3)	0.304	-0.6 (-12.7, 11.4)	0.916
Age (SD)	70.9 (8.6)	70.3 (9.6)	68.4 (7.4)	0.6 (-1.1, 2.4)	0.487	2.5 (0.7, 4.4)	0.007	1.9 (-0.2, 4.0)	0.078

(including UKR) between1 November 2013 to 31 October 2014 were collected. This included age, gender, NZOA score, OHKS and RWS scores. Numbers and scores of patients waitlisted for surgery during the same period and their outcomes were also collected prospectively. This included details and scores of patients returned to GP care.

The historical group, study group and return to GP group were then compared by age, gender, OHKS and RWS. Independent sample t-tests were used to compare means, and the test for a difference in proportions was used to estimate differences between the 3 cohorts (2006–2010, 2013/2014 Surgery, and 2013/2014 Return to GP). The two-sided significance level $\alpha=0.05$ was specified for all statistical tests. Stata software version 13.1 was used for all statistical analyses.

Demand was calculated as in our previous paper by including all publicly funded patients listed for the 12-month study period and adding those performed under ACC, plus all primary joints performed at Mercy Hospital, Dunedin.[6] Hip replacements for fracture were excluded. Unicompartmental knee replacement was included. Bilateral simultaneous procedures were counted as two joints. The population of Otago less Queenstown was taken as 194,800 at June 2013.[15] The New Zealand intervention rate was calculated from Joint Registry data using the New Zealand population as 4,442,100, based on 2013 census data.[15,16]

Unicompartmental knee replacements comprised only 5–9% of knee replacements across the whole study period and so were not analysed separately.

Ethics approval was given by the University of Otago Ethics Committee (Health) for this study.

Results

Demographics

The historical cohort from 2006–10 comprised 613 patients (355 hips (58%) and 258 knees (42%)). It was well matched with respect to age, gender and proportion of hips to knees with the study period (Table 1).

During the study period in 2013/4, 367 primary elective hip and knee replacements were performed. There were 204 hip (56%) and 163 knee (44%) replacements. The mean age was 69.3 years, with hips a little younger than knees (68.5 years vs 70.3 years). The mean NZOA score was 78.8 (hip 79.8, knee 77.7).

A consultant scored 137 patients (37%) who had been given certainty before the start of nurse prioritisation. The PN had scored 230 (63%). There were no significant differences between those scored by nurse or surgeon with respect to age, gender, proportion of hips or knees, NZOA score, Oxford or RWS.

Table 2: Comparison of preoperative Oxford and reduced WOMAC scores (RWS) between surgery 2006-10, surgery 2013/4 and return to GP group 2013/14.

				2006 and 2013 comparison		2006 and 2013 Return to GP comparison		2013 Surgery and 2013 Return to GP comparison	
	2006–10 Surgery	2013/4 surgery	2013/4 Return to GP	Difference (95% CI)	p	Difference (95% CI)	p	Difference (95% CI)	p
Hips									
Oxford	13.6 (6.7)	9.9 (4.9)	13.0 (6.2)	3.7 (2.4, 4.9)	<0.001	0.6 (-1.5, 2.7)	0.577	-3.1 (-4.9, 1.2)	0.001
RWS	31.7 (7.9)	35.2 (6.9)	31.7 (8.5)	3.4 (4.9, 1.9)	<0.001	0.0 (-2.5, 2.5)	0.982	3.4 (0.9, 6.0)	0.008
Knees									
Oxford	15.4 (6.5)	10.6 (3.8)	15.2 (5.9)	4.7 (3.4, 6.1)	<0.001	0.2 (-1.7, 2.1)	0.855	-4.6 (-6.1, -3.0)	<0.001
RWS	28.9 (7.8)	34.3 (6.3)	30.1 (8.2)	5.4 (7.1, 3.6)	<0.001	-1.3 (-3.6, 1.1)	0.290	4.1 (1.7, 6.5)	<0.001
Combined									
Oxford	14.3 (6.7)	10.2 (4.5)	14.2 (6.1)	4.1 (3.2, 5.0)	<0.001	0.1 (-1.3, 1.5)	0.862	-4.0 (-5.2, -2.8)	<0.001
RWS	30.5 (8.0)	34.8 (6.7)	30.8 (8.4)	4.3 (5.4, 3.1)	<0.001	-0.3 (-2.0, 1.4)	0.735	4.0 (2.2, 5.7)	<0.001

During the study period, 608 patients were waitlisted for primary THR or TKR. Four hundred and fourteen (68%) were given certainty for surgery and 194 (32%) were returned to GP care. The return to GP group was younger by 2 years (p=0.027) and had a significantly higher proportion of knee (57%) than the two surgical groups (Table 1). Of the 194 returned to GP, 50 were re-referred and given certainty within the 12-month study period (mean 5 months).

Patient-reported scores

The Oxford scores and RWS scores were significantly worse for both hips and knees in 2013/4 compared with the historical cohort. The difference in Oxford score of 3.7 for hips and 4.7 for knees and RWS (hip 3.4, 11% change from baseline, and knee 5.4, 19% change from baseline) is likely to reflect a clinically important difference.[12,17,18]

The Oxford and RWS scores of those patients returned to GP in 2013/4 were the same as for those receiving surgery in 2006-10 (Table 2).

Demand

During the 12-month study period, 608 patients were waitlisted, 464 patients were given certainty and 367 patients had undergone surgery. The number of patients waiting with certainty had increased from 106 to 164 and the numbers on Active Review had fallen from 83 to 23. Demand was 241 (67%) in excess of supply. Even after sending back 194 patients, the imbalance was 47 joints (13% excess), which rose to 97 (26% excess) when those re-referred and given certainty were included.

During the same period, an additional 8 hip replacements were performed in the hospital under ACC, and 348 hip and knee replacements were performed in the private sector, giving a total of 723 joints performed during the year. The current intervention rate for primary hip and knee replacement in Otago is 371/100,000. The demand, assuming no unmet need in private, is now approximately 495/100,000.

In New Zealand, 16,104 hip and knee replacements, including unicompartmental replacement of knee, were performed in 2014, after excluding those for acute fracture.[16] This gives a New Zealand intervention rate of 363/100,000 for 2014.

Discussion

There will always be excess demand in the public sector leading to the need for some form of prioritisation or rationing. This paper shows that prioritisation is being implemented effectively. Patients undergoing surgery have mean scores that are poorer than those returned to GP. We have previously reported that nurse scoring is as effective as consultant scoring.[11] It removes inconsistencies and accusations of attempts to 'game' the system. However, there are problems around the threshold score.[11]

The patient-derived scores were significantly worse for the study period when

compared with the historical cohort. The return to GP group were similar to those qualifying for surgery in the historical group. Knees were more likely to be returned to GP than hips. This reverses the ratio seen for those qualifying for surgery in both the historical and study group. In general, patients with hip OA are more disabled than knees.[11,19] Knees in the historical group had better scores than hips, but that difference is now less.

The difference on Oxford score of 4.1 points (hips 3.7, knees 4.7) is comparable with the minimum clinical difference of 2 to 5 points reported for the Oxford score.[12,17] Similarly, the change in RWS of 4.3 points (hips 3.4 , knees 5.4) is greater than 6% of maximum (2.9 points) and the 12% change from baseline WOMAC (3.7 points), and therefore is likely to be clinically significant.[18]

There is no absolute value of RWS or Oxford score that indicates the need for surgery. Large series from the UK show an average preoperative Oxford score of 18–20 points for knee replacement .[4,5,20-22] A recent study on unicompartmental replacement showed a mean preoperative OKS of 24 points.[23]

The Oxford scores for hip replacement are a little lower (worse) at 16–19 points,[3,4,20,24-26] with public hospital patients scoring worse than private.[25] In Canterbury, the mean preoperative OHS was 18 in a prospective observational study between 2009 and 2011 of 726 hips.[27]

The mean scores seen in all three groups in this paper are all significantly worse than these studies. They fall into the bottom three deciles for hip, and bottom two deciles for knee, by Oxford score.[12] However, Singleton et al reported similar scores in both Māori (OHKS 10.1, WOMAC 76.2%) and non-Māori (11.26, 73.5%) in the Bay of Plenty between 2005 and 2009.[28]

It has been reported that worse preoperative Oxford scores lead to poorer postoperative scores, though the improvement is greater.[4,12,25] We have not collected postoperative scores on the study group, but have reported postoperative scores similar to New Zealand Joint Registry averages in other studies, especially since introduction of ERAS protocols.[29] We estimated the demand for primary THR and TKR in Otago to be 41.7/10,000 between 2010 and 2012, with 55% of TJR publicly funded.[6] Using the same methodology, the demand in 2014 increased by 18.5% to 49.5/10,000, while both the total number of joint replacements and the intervention rate have fallen slightly.

This figure may still be an underestimate of the need in the community. Behaviour of both GPs and surgeons may have changed, and patients with less severe disease may be less likely to be referred or offered surgery. We introduced a physiotherapy and nurse-led clinic (Joint Clinic) in 2012 in which patients with less severe disease are managed nonoperatively.[30] Approximately 50 patients with Oxford scores less than 20 points were under Joint Clinic care during the study period.

Nationally, the overall intervention rate (all funders) has climbed from 330/100,000 in 2011 to 363/100,000 in 2014.[6] The raw overall intervention rate in Otago of 371/100,000 is similar to the national rate. However, population demographics mean that after age and ethnicity standardisation it is likely to be lower.[31]

New Zealand has a relatively high rate of provision compared with other developed countries. It is predicted to rise to around 600/100,000 by 2026.[1] The increase in demand is less than anticipated in the US and it has been suggested that rather than reflecting over-servicing in New Zealand, it demonstrates a response by the health service to an identified area of high need.[1] Since our original report there has been a lot more publicity about unmet demand for orthopaedic surgery across New Zealand.[10] Nationally, increased numbers of TJR have been performed over this period, but age and ethnicity standardised rates of TJR vary widely across DHBs.[31] We do not think that the situation in Otago is necessarily different from the rest of New Zealand, but we do appear to be several years ahead for a number of reasons. New Zealand has an ageing population, and Otago has a higher proportion of older patients than the New Zealand average.[2,6] We have previously identified the backlog of patients awaiting surgery due to under-provision in previous years as a factor.[6] Despite this, there has been no increase in publicly-funded

surgery in Otago between 2010 and 2014. We estimate 61–65% of TJR are publicly funded based on the National Minimum Data Set (NMDS) and Joint Registry figures. In contrast, only 51% of TJRs in Otago were publicly funded in 2014. This has fallen from 55% in 2010–12. We believe that this difference is due to under-provision in the public sector in Otago rather than over-servicing in private. Many of these patients have chosen to self-fund their procedure due to problems with access to the public sector.

Other centres in New Zealand have reported on unmet demand, with 33% of patients listed for TJR in Northland and 41% in Hawkes Bay declined due to threshold.[10] The average NZOA score in Hawkes Bay for patients qualifying for surgery was 76.9 points, which is similar to ours (78.8), while in Northland it was 70.6 points. However, as no other outcome score was used and multiple consultants scored the patients, it is not clear whether the differences seen in their study are true differences in the incidence and severity of disease, or whether they reflect surgical capacity or different interpretations and use of the scoring tool.

A strength of this study is that all patients in the return to GP group had been prioritised by a single nurse to ensure consistency using the NZOA tool. Criteria for its use were agreed and policed. We have used patient-reported outcome scores to assess the severity of patient symptoms. These are validated scores in common usage. They were not designed as prioritisation tools and it is possible that patients have inflated their scores in an attempt to qualify for surgery.[11,12] However, the Oxford or RWS does not directly influence the NZOA score which was used to determine qualification for surgery. There were still problems with access to TJR in 2006–2010 when we started using these scores and we had no reason to believe that patients were consistently attempting to game the system.

A weakness is that the historical cohort does not include all cases performed between 2006 and 2010. This may result in some bias. However, the historical cohort was well matched with respect to age, gender and proportion of hip to knee with the study period.

It has been predicted that the demand and projected numbers of hip and knee replacement will rise significantly.[1,2] It is unclear how this can be funded. While the budget announcement of increased numbers of TJR from 2016 onward is welcome, the numbers are inadequate to match demand. The indicative increase of Southern DHB (including Southland) is provisionally for only 62 extra joints spread over 3 years. The onus therefore is on individual DHBs to decide the allocation of their scarce resources. If orthopaedic volumes are not increased, then other orthopaedic procedures will need to be cut if additional joint replacements are to be done. The alternative is to raise thresholds for TJR to an unacceptable level to achieve ESPI compliance.

Prioritisation and process change may help efficiency and allow more timely surgery. However, the 4-month target is artificial and by itself does nothing to increase capacity. The worst patients may be getting their surgery sooner, but there is no sign that the numbers of severely affected patients is decreasing.

The public needs to be given realistic expectations. There is explicit rationing and, although cost effective, public funding for hip and knee replacement will soon only be for the most severely affected. Others need to consider private insurance, or self-funding their surgery.

Conclusion

Patients undergoing primary elective total hip and knee replacement in Otago in 2014 are more severely disabled than between 2006–2010. Patients currently being returned to GP would have qualified for publicly-funded surgery during that period. The unmet demand for TJR in Otago has increased by 19% since 2012.

This paper confirms that the increasing demand that is not matched by an increase in supply leads to a recognisable and measurable increase in the severity of disease using validated patient-reported measures in patients qualifying for surgery. The problems we describe are likely to become increasingly widespread across New Zealand.

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The outcomes of patients returned to general practitioner after being declined hip and knee replacement

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ABSTRACT

AIM: To determine the outcome of patients waitlisted for hip and knee replacement surgery who were returned to GP due to resource constraints.

METHODS: Prospectively gathered data of all patients returned to GP was analysed, including demographics, clinical prioritisation scores and patient-reported scores. Subsequent outcome was collected from departmental records and the National Joint Registry.

RESULTS: Between November 2013 and December 2015, 374 patients were returned to GP care. At minimum 12-month follow-up, 215 (57.5%) had undergone or had certainty for surgery, 36 patients (9.6%) had been re-referred and again declined surgery and 123 (32.9%) remained in GP care. The factors influencing the likelihood of a patient subsequently qualifying for surgery were need for hip rather than knee replacement, time from initial FSA and initial NZOA score. The mean waiting time for those patients who underwent publicly-funded surgery was 14.7 months.

CONCLUSION: Returning patients to GP delays treatment rather than reducing the need for surgery. This delay results in waste, added costs to the patient, healthcare system and society, and may reduce the benefit of surgery. There needs to be a significant increase in capacity to meet this demand.

In New Zealand it is recognised that the public sector is not able to fully cope with the demand for publicly-funded elective surgery. District health boards (DHBs) are required to prioritise patients and operate on those most in need. However, they are also obliged to meet Elective Surgery Performance Indicators (ESPIs). One of these (ESPI 5) stipulates that no patient should wait longer than four months once given certainty for surgery by the DHB. The original target of six months was reduced to five months in June 2013 and four months in December 2014. If there is insufficient capacity for the operation to be completed within this timeframe then a patient cannot be given certainty. If they fall just below this 'financial threshold' and are likely to deteriorate and meet the threshold within the foreseeable future they can be classed as Active Review (AR). This requires regular follow-up by the service. Otherwise they are declined and returned to their general practitioner (GP) for ongoing care.

Total hip and knee replacement (THR, TKR) are two of the most widely performed and cost-effective elective surgical procedures with approximately 10,000 procedures performed per year in New Zealand.[1] Despite increases in numbers of publicly-funded procedures, the rate has had a minimal increase between 2007 and 2013.[2] This has resulted in demand outstripping capacity and the need for explicit rationing with up to 32–41% of patients being declined total joint replacement (TJR) and returned to GP.[3–6] The outcome of these patients returned to GP is currently not known. Anecdotal experience suggests that more patients are choosing to self-fund their

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procedures in the private sector. Preliminary research findings suggests that at least 25% of patients returned to GP are re-referred soon after being declined.[3,4]

The primary aim of this study was to determine the outcome of the return to GP group at minimum 12-month follow up after their initial orthopaedic outpatient appointment. Secondary outcome measures were to determine predictors of re-referral and the time from initial clinic appointment until surgery if subsequently undertaken.

Methods

In November 2013 we commenced a system whereby all patients waitlisted for hip or knee replacement by an orthopaedic surgeon at a first specialist assessment (FSA) were independently scored by a single prioritisation nurse using the New Zealand Orthopaedic Association hip and knee priority scoring tool (NZOA score).[3] Details of the tool and process have been previously described.[3,4] The threshold score was set at 71 points (0 best to 100 worst) based on the expected capacity of the orthopaedic service. Any patients who scored above the threshold would be given certainty for surgery with an expectation that the surgery would be completed within four months. If a patient scored below the threshold score they could be given a clinical over-ride by their surgeon, or were returned to GP for ongoing care. A decision had been made that no patients were to be classed as active review. The NZOA score has been compared with patient-reported outcome scores and found to be an effective tool, though patients just below the threshold score may not have a clinically important difference from those above threshold.[3]

Pre-operative patient-reported outcome scores (Oxford Hip or Knee Score (OHS, OKS)[7] and a Reduced Western Ontario and McMaster Osteoarthritis Index (WOMAC) score (RWS)[8,9] were collected prospectively as part of the prioritisation process. The Oxford score has 12 questions and is scored 0 to 48 where 0 is worst, The RWS has 5 pain and 7 function questions and is scored 0 to 48 where 48 is worst.

The cohort of patients returned to GP between November 2013 and December 2015 was identified via a record kept prospectively by the prioritisation nurse. Their subsequent outcome was determined from this database with further information, including gender and ethnicity collected from Southern District Health Board's (SDHB) patient record software and clinical notes. There was a minimum 12-month follow-up period after the date of their FSA. Patient details were cross referenced with the New Zealand Joint Registry, which has 98% compliance in New Zealand to check whether TJR was performed in other hospitals.[1]

The outcomes of these patients were categorised to one of four categories: remain with GP, below threshold, private or surgery. Patients classified as remain with GP were those that had been declined surgery and had not been re-referred by their GP for reassessment. Those classified as below threshold were those that had been re-referred but still did not meet the threshold for elective surgery and were again returned to GP. The private group were those who had been declined through the public system, and self-funded surgery in the private sector. Patients classified as surgery were those that had received publicly-funded surgery after being returned to their GP.

The wait times of the surgery group from their initial FSA to eventual certainty decision, and from FSA to surgery, were collected. Comparisons were made between the first and second year of the study period, and between hips and knees.

Statistical analysis was performed with the help of a biostatistician. Associations of sex and age with the outcome group were assessed using the chi-square test for independence and Analysis of Variance (ANOVA) respectively. ANOVA was also used to investigate associations between the outcome group and each of the NZOA, OHS or OKS score and WOMAC scores. Chi square tests were used to compare outcomes between sub-groups.

Ethics approval was obtained from the University of Otago Ethics committee (Health).

Results

During the period covered by this study, 374 patients were returned to GP after being waitlisted for THR or TKR and scored by the prioritisation nurse. Demographic details are given in Table 1. The mean age across

all groups was 67.5 years with patients requiring THR on average almost four years younger than those requiring TKR. The mean time from FSA to the time of this review was 24.2 months (12 to 37 months). The same number of patients (187) had been returned in each of the two years of the study. During the same period, 832 primary elective hip and knee replacements were performed at our institution.

Table 1: Demographic details of the 374 patients returned to general practitioner (GP).

Number	374	
Age	67.5 (sd 10)	
Gender		
Male	171 (45.7%)	
Female	203 (54.3%)	
Joint		
Hip	156 (41.7)	
Knee	218 (58.3)	
Scores at initial FSA		
NZOA (0–100)	63.1 (6.5)	
OKS (0–48)	14.5 (5.5)	
OHS (0–48)	14.0 (5.3)	
RWS (0–48)	31.2 (7.2)	
Duration of follow up from initial FSA (mean, range, months)	24.2 (12–37)	
Year 1 (n, mean, range,)	187	30.7 (25–37 months)
Year 2 (n, mean, range,)	187	17.6 (12–24 months)

FSA; First specialist assessment, NZOA; New Zealand Orthopaedic Association hip and knee prioritisation score, OHS; Oxford hip score, OKS; Oxford knee score, RWS; Reduced WOMAC score.

Of the 374 patients, 122 (32.6%) remained in the community without any further contact. A further 36 (9.6%) patients had been re-referred by their GP to see the specialist for another clinical assessment and had again failed to meet the financial threshold for elective surgery. Two patients had died: one in each of the above groups.

Over half of the sample had received or were awaiting surgery across either public or private sectors. One hundred and ninety-four patients (51.9%) had undergone or were awaiting public elective surgery with 22 patients (5.9%) electing to self-fund private surgery (Table 2).

Patients awaiting hip replacement were significantly more likely than those awaiting knee replacement to have subsequently qualified for public surgery [100 of 156 (64%) vs 94 of 218 (43%) (Chi square 19.7, p<0.0001)]. Conversely, knees were more likely than hips to remain in GP care without re-referral: [87 of 218 (39.9%) vs 35 of 156 (22.2%) chi square 12.6, p<0.0001)]. An equal number of hips and knees had their surgery in the private sector (Table 2).

Table 2: Outcomes of patients initially returned to general practitioner (GP) at minimum 12-month follow up.

Outcome	All patients (%)	Hips	Knees
Remain with GP	122 (32.6%)	35 (22%)	87 (39.9%)
Below threshold	36 (9.6%)	10 (7%)	26 (12%)
Private	22 (5.9%)	11 (7%)	11 (5%)
Surgery	194 (51.9%)	100 (64%)	94 (43%)
Total	374	156	218

Patients in the surgery group had follow-up of 26.4 months compared to 20.7 months in the remain with GP group. Patients seen in year 1 were more likely to have certainty for surgery (121/187, 64.7%) than those in year 2 (73/187, 39%) (chi square 24.7, p<0.0001). Conversely, significantly more patients remained in GP care from year 2 (86 of 187 (46%) compared with year 1 (36 of 187, 19.3% chi square 30.4, p<0.0001). There was no significant association between sex and patient final outcome (p=0.31) nor age and patient final outcome (p=0.77).

The surgery group had the highest mean initial NZOA score, as well as the worst mean Oxford and reduced WOMAC (RWS) scores. There was a significant association between mean patient NZOA score and

patient final outcome (p<0.01). Any association between patient outcome and mean Oxford (p=0.10) or RWS (p=0.08) did not reach significance (Table 3).

Table 3: Scores at time of initial first specialist assessment (FSA).

Outcome	NZOA mean (sd)	RWS/48 (sd)	OHS, OKS/48 (sd)
Remain with GP	61.8 (6.4)	30.4 (7.3)	15.1 (5.6)
Below threshold	60.4 (9.2)	29.6 (8.1)	15.1 (5.3)
Private surgery	62.4 (8.2)	30.6 (8.8)	14.4 (7.4)
Surgery	64.2 (5.8)	32.4 (6.6)	13.4 (4.9)

NZOA; New Zealand Orthopaedic Association hip and knee prioritisation score, OHS; Oxford hip score, OKS; Oxford knee score, RWS; Reduced WOMAC score.

Of the 115 patients with an initial NZOA score of 70 points (a common score just below the threshold), 76 (66%) subsequently gained certainty compared with 88 of 201 (44%) with a lower score (chi square 14.6, p<0.0001).

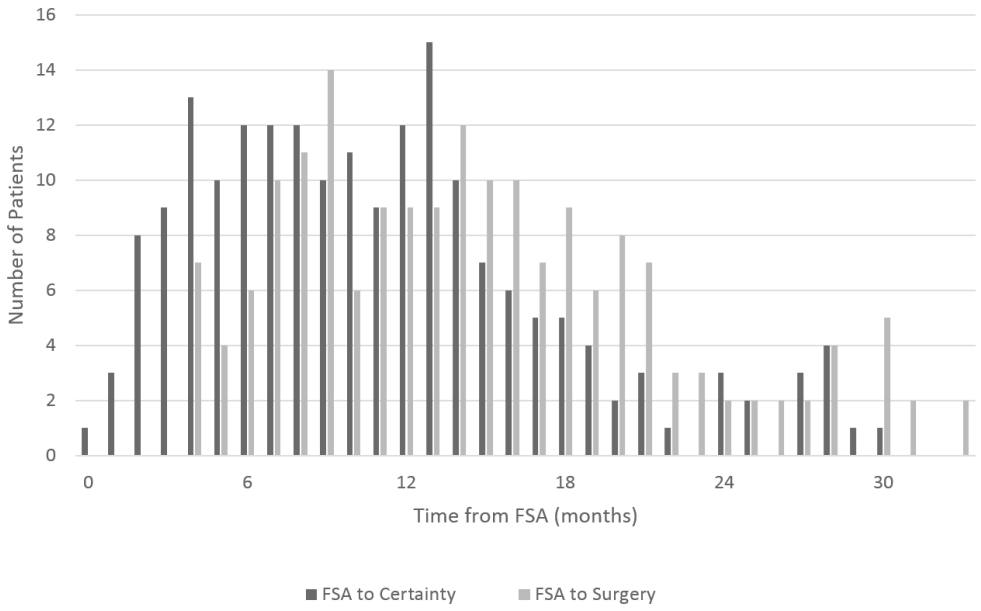
The mean waiting time from initial FSA to certainty date was 11 months (sd 6.6, median 10 months) (range 1–30 months).

The mean time from FSA to surgery was 14.7 months (sd 6.9, median 14) (range 4–33 months). Thirteen people had received certainty but were yet to undergo the proposed surgery. The mean time from the certainty decision to surgery was 3.7 months (sd 3.3, range 1–23 months) (Figure 1).

Discussion

In this study over a two year period, 374 patients who were recommended TJR by their surgeon were declined for surgery due to capacity constraints in the public health system and therefore returned to GP care. This equates to approximately 31% of patients waitlisted for surgery and has not changed from our previous paper.[3] This is supposed to give patients certainty and allow them to make choices. These are essentially limited to: wait until they deteriorate, go private or request reassessment. Only 22 (5.9% of all patients returned) elected to self-fund in the private sector, which reflects the demographic of this population with few patients having the funds for a private operation. Those who can afford to self-fund tend to bypass the public system altogether. Two hundred and thirty (61.5%) were re-referred during the study period of which 194 (51.9% of all returns) went on to receive surgery and 36 (9.6%) again failed to meet the financial threshold

Figure 1: Time from first specialist assessment (FSA) to certainty decision and to surgery.



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for elective surgery. Only a third (122, 32.6%) remained in the community without any further referral.

The factors that had the greatest influence on the likelihood of a patient subsequently qualifying for surgery were initial NZOA score, hip rather than knee disease and the length of time from initial FSA. This is not surprising and reflects the natural history of these conditions, which is to slowly deteriorate. Patients with hip osteoarthritis are typically more disabled than those with knee osteoarthritis and less likely to respond to non-operative interventions.[3,10] The surgery group had the worst patient-reported scores (OHS,OKS and RWS) at initial assessment but the trend did not reach statistical significance. The patient-reported scores of the patients (OHS 14.0, OKS 14.5, RWS 31.2) are a level similar to those who had received surgery between 2006 and 2010 in our institution[4] and worse than the average scores reported in the literature for primary hip and knee replacement in other centres in New Zealand or overseas.[11–20] However, during the period of the study the mean scores of patients undergoing surgery in our institution were OHS 9.9, OKS 10.6 and RWS 34.8.[4] This demonstrates that those patients returned to GP were a slightly less severe group than those qualifying for surgery, confirming that the prioritisation was robust.

Prior to this study we had used active review (AR) widely with 162 patients waiting for TJR on AR in August 2012.[5] Patients remained within the system and could be assessed by use of experienced nurses and patient-reported questionnaires. This created an increasing amount of work for the service and their visibility was a potential embarrassment for DHB management, the Ministry of Health and politicians. It was decided when we commenced nurse prioritisation that active review was no longer to be used. As two-thirds of patients scoring 70 points subsequently qualified for surgery the continued use of AR would have been justified and it would have avoided the additional delay, costs and administration of re-referral from a GP. The majority of patients (63%) in the surgery group got certainty for surgery within 12 months of initial FSA. Most of these patients will have waited until their initial decline decision, waited and paid for a further GP appointment and potentially waited 4–6 months for a further FSA.

The demand for TJR is increasing in New Zealand and around the world.[21,22] However, between 2007 and 2013 there was there was no increase in the rate of publicly funded elective primary hip and knee replacement in New Zealand although the total numbers of joint replacements increased.[2] The demand for TJR in our area appears to be higher than the New Zealand average but the problems we are seeing are not unique.[3–6]

The reduction of the Ministry of Health's target from six months to four months does little to facilitate patient care.[4] While those accepted onto the waitlist will get their surgery sooner, it does not increase the numbers of procedures done. Because failure to meet the target may be associated with financial penalties to the DHB, the unintended consequence is that more patients are being returned to GP purely to meet the target.[6,21,23] They do not show up on waiting lists so are invisible.

In this study the mean time from certainty to surgery was 3.7 months. However, the real wait time for those patients initially returned to GP who ended up qualifying for public surgery was 14.7 months. The remaining patients are still waiting at an average of 21 months following FSA. Waiting for surgery has an adverse effect on outcomes. Studies have consistently shown that worse pre-operative scores are associated with poorer post-operative results, though the improvement in score may be greater.[7,11,16,17] Waiting longer than six months can cause a 50% decrease in the odds of achieving a better than expected functional outcome compared with those who waited less than six months.[24] It is not clear if this is happening in our practice as we have no comparable controls. Following introduction of an enhanced recovery programme, our post-operative Oxford hip scores compared to the New Zealand average are worse (38.8 vs 40.4) but the OKS is a little better (39.8 vs 37.5) despite poor pre-operative scores (11.1).[1,25]

Total hip replacement and total knee replacement are two of the most cost-effective procedures in orthopaedic surgery.[11,15] By returning patients back to

the care of their GP rather than operating, there is a substantial and avoidable loss of quality-adjusted life years.[16] There may be increased medical costs for non-operative treatment and its complications, such as gastro-intestinal bleeds from non-steroidal anti-inflammatory use, and increased in-patient costs due to increased complexity of surgery, length of stay and risk of complications. In addition there are personal costs to the patient and societal costs, which are harder to quantify.[26,27]

Rolfson et al estimated the cost of waiting for hip replacement in Sweden as US$7,666 per patient per year.[26] Fielden et al calculated the mean cost was NZ$1,030 (US$688) per person per month waiting (2005 figures).[27] Societal costs made up over 70% of this even in those who were not in paid employment. If we extrapolate these figures (but still using 2005 values and exchange rates) to our cohort then the additional cost of waiting more than six months for surgery in those who were initially returned but who subsequently underwent publicly funded surgery was NZ$1.6 million (US$1.1 million). The cost of those still waiting is a further NZ$2.6 million (US$1.7 million). Index-linking would increase these figures by 26% to NZ$2 million and NZ$3.25 million.[28] As the current costing for an uncomplicated publicly funded hip or knee replacement is approximately $16,000 using WIESNZ15 cost-weights, this could have funded an additional 328 joint replacements at 2015 values.[29]

A limitation of this study is that it is not clear what has happened to the third of patients who remain in primary care without re-referral or surgery. The natural history of the condition is a slow deterioration. They may have given up, modified their expectations or developed intercurrent medical problems that preclude surgery. Only two patients had died. Further research would be helpful in this area but was outside the initial scope of this project. We had hoped to look at outcomes among Māori and Pacific patients. However, only three of the 374 were of Pacific ethnicity, and six were Māori, meaning ethnic specific analyses were not possible. We have previously shown higher rates of publicly funded TJR provision in Māori than New Zealand European and slightly lower rates in Pacific people.[2] It appears that Māori and Pacific people are not over-represented in the return to GP group. Finally, the NZOA hip and knee prioritisation score used in this study has recently been superseded by a new generic score that includes a patient impact on life score. Patients with hip and knee OA will now be scored directly against patients with other orthopaedic conditions. This is likely to have an effect on the numbers and mix of patients returned to GP.

Conclusion

In our district and across New Zealand, the demand for TJR has increased, there has not been a corresponding increase in service provision and the target time allowed by the Ministry of Health for surgery has decreased. This has resulted in many patients being declined surgery despite reaching the clinical threshold for joint replacement. Those qualifying for surgery are more severely affected than in past years. Returning patients to GP delays treatment rather than reducing the need for surgery. Over half of patients returned to GP care in order to meet the four-month target will end up qualifying for surgery with a mean waiting time of 14.7 months from initial FSA. This delay results in waste, added costs to the patient, healthcare system and society and may reduce the benefit of surgery. Only 5.9% of patients returned to GP elected to pay for private surgery. Less than a third of patients remain in primary care without further referral or surgery. Further work is required to determine the fate of this group. There needs to be a significant increase in capacity in our district to meet this demand.

Competing interests:
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Original research

The Relationship Between Preoperative Oxford Hip and Knee Score and Change in Health-Related Quality of Life After Total Hip and Total Knee Arthroplasty: Can It Help Inform Rationing Decisions?

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ABSTRACT

Background: In countries with publicly funded health care, there is an increasing need for explicit rationing for total joint arthroplasty (TJA). The Oxford Hip and Knee Scores (OHS/OKS) have been used to set access thresholds for TJA despite not being developed for that purpose. The aim of this study was to determine whether preoperative OHS/OKS can aid rationing decisions by investigating the changes in general health-related quality of life after TJA.

Methods: OHS/OKS, Short Form-12, and Short Form-6D (SF-6D) scores were collected preoperatively and at 1 year postoperatively in a cohort of patients undergoing total hip arthroplasty (THA; n = 713) and total knee arthroplasty (TKA; n = 520). The association between preoperative OHS/OKS and postoperative score and the change in OHS/OKS and SF-6D was investigated, adjusting for age and gender.

Results: The mean Oxford scores improved from 13.9 to 40.7 (OHS) and 15.6 to 37.4 (OKS). The mean SF-6D improved after THA (0.53 to 0.80) and TKA (0.56 to 0.78) (all $P < .0001$). Poorer preoperative Oxford scores were associated with poorer postoperative OHS/OKS and SF-6D but larger improvements. For every 5 points lower preoperative OHS/OKS, the postoperative SF-6D score was worse by a margin of 0.019 (THA) and 0.023 (TKA).

Conclusions: Preoperative OHS/OKS can help inform rationing decisions. A lower preoperative OHS/OKS will result in greater gains but a lower final outcome score in general health-related quality of life.

Introduction

Total hip arthroplasty (THA) and total knee arthroplasty (TKA) are very successful interventions for end-stage osteoarthritis (OA). With an aging population and rising rates of obesity, the demand for THA and TKA is increasing [1,2]. In countries with limited publicly funded health care, there is an increasing need for explicit rationing [3,4]. Almost half of National Health Service trusts in the United Kingdom are now rationing THA and TKA [5]. There are concerns that delaying surgery until a patient has deteriorated to a threshold score may have a deleterious effect on their final outcome [6], which could be seen as an unintended consequence of rationing.

In New Zealand, Ministry of Health policy requires District Health Boards to complete surgery within 4 months of a decision to offer publicly funded surgery. Those patients who cannot, due to capacity constraints, be operated on within 4 months are declined surgery and returned to the care of their general practitioner (GP). Since 2000, various tools or scoring systems have been used to help prioritize patients with the emphasis on offering surgery to those patients with the worst symptoms. These tools have been validated and shown to be effective but lack discrimination around the threshold score [4]. They are not designed to assess outcomes after surgery.

Condition-specific scores such as the Oxford Hip Score (OHS) and Oxford Knee Score (OKS) were originally developed to assess outcomes after joint replacement [7]. They have been used in some regions in the United Kingdom to determine eligibility for surgery

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despite not having been designed for that purpose and not shown to be predictive of patient satisfaction after THA and TKA [8].

In addition to condition-specific scores, generic health-related quality of life (HRQoL) measures such as the Short Form-12 (SF-12) [9], the Short Form-6D (SF-6D) [10], and the Euroquol-5D [11] can be used to assess outcomes. The SF-12 [9] has 12 questions covering 8 domains: physical functioning, role participation (physical and emotional), social functioning, bodily pain, mental health, general health, and vitality. It is usually reported as a physical component score (PCS) and a mental component score (MCS). The SF-6D [10] is a preference-based single-index measure of health, derived from the SF-12, which can be used to calculate quality-adjusted life years for use in cost-utility analysis. The SF-6D focuses on 7 of the 8 health domains covered by the SF-12, with only the general health domain not included. The EQ-5D [11] is a preference-based HRQoL measure that describes health across 5 dimensions—mobility, self-care, usual activities, pain/discomfort, and anxiety/depression and is also commonly used in cost-utility analysis.

An advantage of generic HRQoL measures is they can be used to compare outcomes of procedures within orthopaedics or with other specialties, which may help inform resource allocation in a publicly funded health system.

The aim of this study was to determine whether preoperative OHS/OKS can help inform rationing decisions by investigating the changes in general HRQoL after THA and TKA.

Material and methods

Data Set

This cohort study comprises 1233 patients who underwent THA (n = 713) or TKA (n = 520) at our institution between 2006 and 2010. Patient demographic data including the age, sex, and joint replaced were collected. Patient-reported scores (OHS/OKS and the SF-12) were collected preoperatively and postoperatively (at approximately 1 year) using an arthroplasty audit database (OrthoWave, Stryker, Sydney, Australia). SF-12 PCS and MCS and SF-6D scores were calculated using responses to individual questions from the SF-12 [9,10]. To enable comparability with results from other studies, we also report EQ-5D-3L scores that were mapped from the SF-12 scores [EQ-5D(SF-12)] using a published crossover algorithm [12]. The SF-6D has half the range of the EQ-5D-3L and a correspondingly lower minimum important difference (MID) (0.041) than the EQ-5D (0.074) [13]. The MID for OHS and OKS was taken as 5 points [14]. The MID for SF-12 PCS and MCS was also taken as 5 points [15].

Statistical Analysis

Patients were grouped into 5 bands based on their preoperative Oxford score: <10, 10-14, 15-19, 20-24, and over 25 points. For both THA and TKA, preoperative and postoperative mean and standard deviation were calculated for each patient-reported outcome measure. The change in scores (postoperative minus preoperative) was tested using a paired *t* test.

The association between preoperative Oxford scores and postoperative Oxford, SF-12 PCS and MCS, and SF-6D scores was assessed graphically by plotting the postoperative score and the change in score, for each outcome measure, against preoperative Oxford scores. Curves were fitted using robust locally weighted regression smoothing to visualize the relationship between preoperative and postoperative outcomes [16]. Linear regression, adjusted for age and sex, was used to estimate postoperative outcome scores and change in scores, conditional on preoperative Oxford score, for the THA and TKA cohorts. All statistical analyses were conducted using *R* version 3.5.1 [17].

Results

Baseline data were collected from patients who underwent a THA (n = 713) or a TKA (n = 520). Follow-up surveys were completed at a mean of 13 months postoperatively by 945 patients (THA [n = 569]; TKA [n = 375]), a completion rate of 77%. There were no significant differences in age, sex, or baseline measures between those completing and those not completing the follow-up survey. Most patients were female, with no significant difference in gender mix between THA and TKA patients ($P = .18$). Patients with hip OA were approximately 3 years younger and had poorer preoperative Oxford ($P = .0001$) and SF-6D scores ($P = .0006$) than patients with knee OA but had no significant difference in SF-12 PCS ($P = .64$) or MCS ($P = .08$).

After surgery, there was a significant improvement in all mean unadjusted outcome scores for both THA and TKA ($P < .0001$) (Table 1). Unadjusted mean scores after THA were significantly better than those after TKA for Oxford scores (3.3, $P < .0001$) and SF-12 PCS (2.2, $P = .009$). There was no significant difference in the postoperative score between THA and TKA cohorts for SF-12 MCS (0.6, $P = .4$), SF-6D (0.02, $P = .063$), or EQ5D (SF-12) (0.028, $P = .067$). The mean improvement was greater for THA than TKA on all scores including OHS/OKS (5, $P < .001$), SF-6D (0.05, $P < .001$), and EQ-5D(SF-12) (0.078, $P < .001$) (Table 1).

Patients with a lower preoperative Oxford score achieved a lower mean postoperative Oxford score, SF-12 PCS, SF-12 MCS, and SF-6D than those with higher preoperative scores, after both THA and TKA. The improvement (gain in scores) was greater in those with lower preoperative scores on all outcome scores (Fig. 1, Table A1).

In adjusted regression models, age was a significant (but nonlinear) predictor of postsurgery improvement in outcome scores for Oxford, SF-12 PCS, and SF-6D for both hips ($P < .001$) and knees ($P < .04$) but not for SF-12 MCS ($P > .15$). (Figure A1). The improvement in OHS was greatest in patients aged 60 years and in OKS for patients aged 70 years. The gain in SF-6D utility was greater in younger patients and declined with increasing age especially after 70 years. Men had significantly smaller improvements than women in Oxford scores for hips ($P = .007$) but not knees. There was

Table 1
Patient-reported outcome measures before and 1 y after joint arthroplasty surgery.

Outcome measure	Preoperative	Postoperative 1 y	Change[d]
	Mean (SD)	Mean (SD)	
Total hip arthroplasty (THA)			
Total Oxford score	13.9 (6.6)[b]	40.7 (7.3)[b]	26.8 (9.2)[b]
SF-12 PCS	28.1 (5.3)	43.5 (11.0)[a]	15.4 (10.9)[a]
SF-12 MCS	43.0 (12.0)	54.4 (9.4)	11.4 (12.8)[c]
SF-6D utility value	0.53 (0.11)[b]	0.80 (0.15)	0.27 (0.17)[b]
EQ-5D from SF-12	0.383(0.22)[a]	0.775 (0.20)	0.392 (0.25)[b]
Total knee arthroplasty (TKA)			
Total Oxford score	15.6 (6.1)[b]	37.4 (8.2)[b]	21.8 (9.3)[b]
SF-12 PCS	28.3 (5.3)	41.3 (10.4)[a]	13.0 (10.3)[a]
SF-12 MCS	44.7 (11.4)	53.8 (9.6)	9.2 (11.8)[c]
SF-6D utility value	0.56 (0.10)[b]	0.78 (0.15)	0.22 (0.15)[b]
EQ-5D from SF-12	0.433 (0.20)[a]	0.747 (0.19)	0.314 (0.25)[b]

[a] Indicates difference between the THA and TKA groups is statistically significant $P < .01$.
[b] Indicates difference between the THA and TKA groups is statistically significant $P < .001$.
[c] Indicates difference between the THA and TKA groups is statistically significant $P = .02$.
[d] All changes (preoperative to postoperative) are highly statistically significant ($P < .0001$).

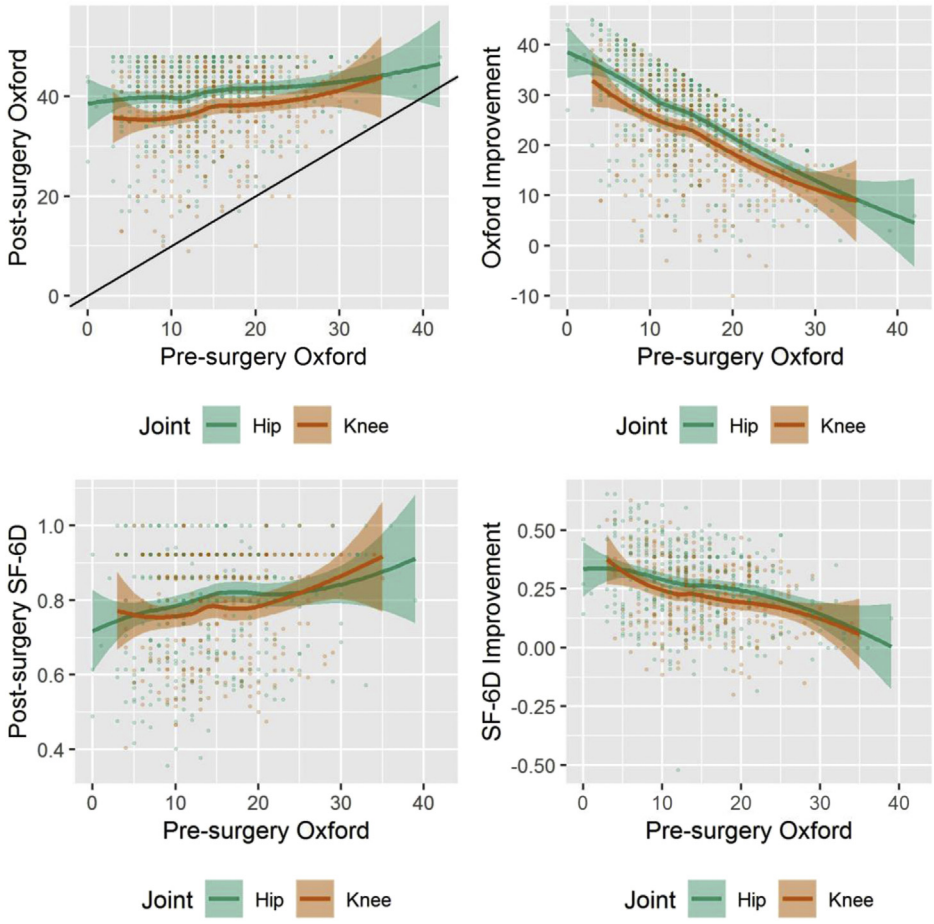

Figure 1. Postsurgery and improvement in total Oxford Hip or Knee Score and SF-6D utility 1 y after surgery, by presurgery total Oxford score (unadjusted with 95% confidence intervals).

no significant difference between men and women for SF-12 or SF-6D outcomes.

After adjusting for age and gender, the mean postoperative Oxford, SF-12 PCS, and SF-6D scores for both THA and TKA were significantly lower for those with poorer Oxford scores at baseline (Table A1). The difference in mean scores between the poorest preoperative group (OHS/OKS<10) and the best preoperative group (OHS/OKS>25) was OHS 3.9, OKS 4.6 points, SF-12 PCS 5.0 (THA), 5.4 (TKA), SF-6D 0.08 (THA), and 0.10 (TKA).

In the continuous regression model, the postoperative OHS was 0.8 points and OKS 1.2 points poorer for every 5-point difference in preoperative OHS/OKS (Fig. 2a). Similarly, for SF-6D, the postoperative score was worse by 0.018 (THA) and 0.023 (TKA) for every 5-point decrease in preoperative OHS/OKS (Fig. 2c). The difference in change in the Oxford score between THA and TKA was statistically significant for all preoperative OHS/OKS <28 points (Fig. 2b). A similar pattern was seen for the gains in SF-6D score according to preoperative OHS/OKS but was not statistically significant because of wide confidence intervals (Fig. 2d).

Discussion

Our results show significant improvement in HRQoL at 1 year after THA and TKA. The postoperative SF-6D and EQ-5D(SF-12) scores after THA and TKA are comparable; however, there is a significantly larger gain after THA than TKA on all outcome scores. A poorer preoperative OHS/OKS is associated with a lower HRQoL score at 1 year, compared with higher preoperative scores. There was a clinically important difference in postoperative SF-6D scores between the groups with the lowest and highest preoperative Oxford scores, after adjusting for age and gender, that is, more than the MID reported for SF-6D [13]. This suggests that a clinically relevant poorer HRQoL outcome may result from rationing access to arthroplasty on the basis of lower Oxford scores. However, larger HRQoL gains were associated with lower preoperative Oxford scores. These findings are relevant to health services such as ours, in which the use of explicit rationing over recent years has led to the mean preoperative OHS/OKS score falling to around 10 points in our institution [3,4].

It is well established that, for both THA and TKA, lower preoperative Oxford scores are associated with a lower postoperative Oxford score and a higher change in score [7,18-20]. Less has been published on generic HRQoL measures, with most studies reporting EQ-5D scores. Our results show that the mean improvement in SF-6D in our patients after both THA (0.27) and TKA (0.22) is well above the MID of 0.041. This is higher than that previously reported [21-23], mainly due to lower preoperative SF-6D in our cohort. The mean EQ-5D(SF-12) score also improved significantly from 0.383 to 0.775 (a gain of 0.392) after THA and from 0.433 to 0.747 (+0.314) after TKA. These scores and changes were similar or greater than results reported in other studies using the EQ-5D [18,24-26].

Dakin et al reported an improvement in the mean EQ-5D score from 0.39 to 0.71 (+0.32) after TKA, with the greatest gains in those with an OKS in the lowest quintile (OKS <12) [18]. Subsequently,

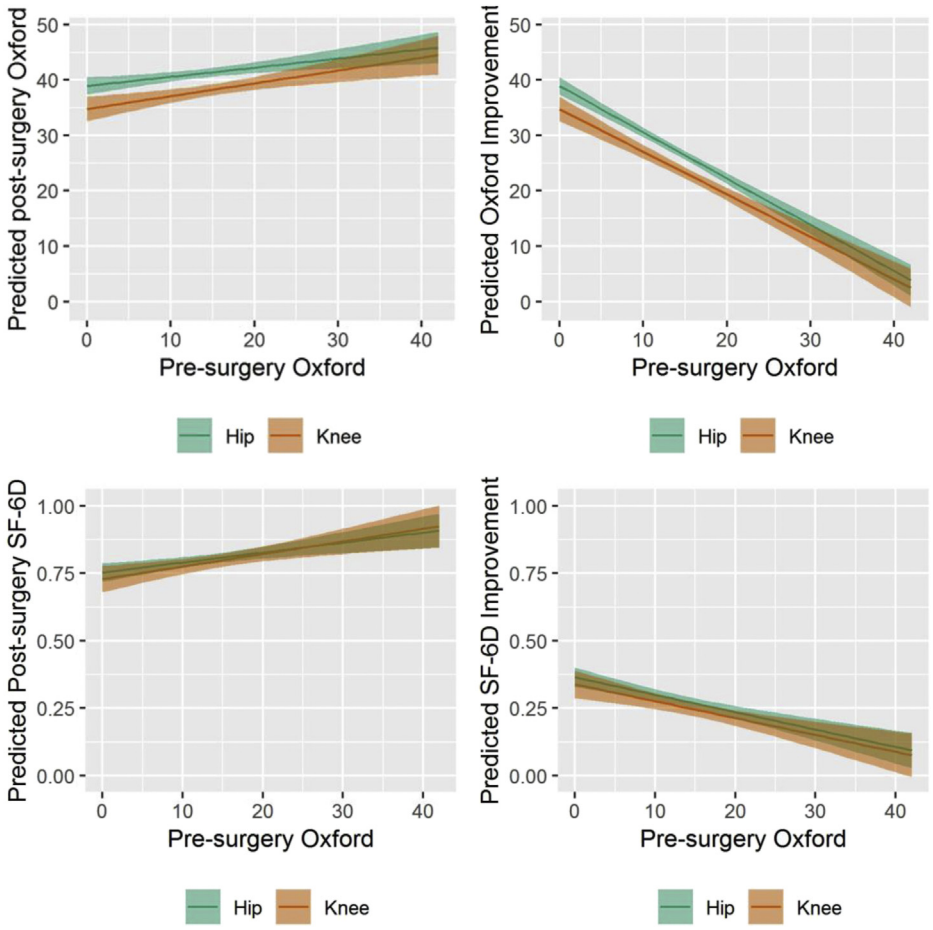

Figure 2. Postsurgery and improvement in total Oxford Hip or Knee Score and SF-6D utility 1 y after surgery, by presurgery total Oxford score (adjusted for age and gender).

Eibich et al. [19] reported similar findings after THA and TKA, also demonstrating that gains in HRQoL (as measured by the EQ-5D) were still evident in patients with preoperative OHS >46 and OKS >44 [19]. Gordon et al. [27], using data from the Swedish hip registry, also reported lower preoperative scores were associated with poorer postoperative EQ-5D scores. Our results, in a sample with poorer mean preoperative scores confirm that a larger gain in HRQoL results in patients with poorer preoperative OHS/OKS, but at a lower final EQ-5D score.

These findings have implications on the cost-effectiveness of total joint arthroplasty in relation to preoperative status. Dakin et al. [18] suggested that if TKAs were to be rationed based on the magnitude of HRQoL gains, OKS would be a reasonable tool to use to set the threshold. They suggested that the most cost-effective preoperative OKS was 12-15 points, but TKA remained cost-effective even in patients with an OKS up to 35-40 points, depending on the American Society of Anesthesiologists grade. Schilling et al concluded that TKA was likely to be cost-effective for most patients except those with an unusually high HRQoL [26]. Ferket et al. [28] found only small improvements in SF-12 PCS (+1.7) and SF-6D HRQoL scores after TKA (+0.008). They suggested that TKA would be more effective if restricted to patients with SF-12 PCS <50 and was most attractive from an economic viewpoint in patients with a score <35 points. In contrast, the mean preoperative PCS in our study was 28.3, with a clinically relevant improvement of 13 points.

Consistent with other reports [19,25], we found greater improvement in OHS/OKS after THA than TKA. The differences in change in OHS/OKS (5 points), SF-6D (0.050), and EQ-5D(SF-12) (0.078) are at or above the reported MID for these scores [13,14]. Our results suggest that to achieve a similar gain in both Oxford score and HRQoL at 1 year, a patient with knee OA should have an Oxford score 3-4 points worse than a patient with hip OA. This was statistically significant for the Oxford score but did not reach statistical significance for SF-6D utility despite showing the same pattern. Jenkins et al reported similar findings with patients undergoing TKA needing an OKS 8 points lower than for a patient undergoing THA to offer the same value for money over a patient's lifetime [25]. This gives some limited support to prioritizing THA over TKA.

Oxford scores alone should not be used to determine access to THA and TKA. Patient-reported scores such as the Oxford score may be open to "gaming" by a patient or referring GP if it becomes known that they are being used to determine whether a patient qualifies for surgery. The decision to offer surgery is complex and should involve clinical and radiological assessment of the patient by an orthopaedic surgeon. Increasingly, however, some form of gate-keeping is required, which may be by surgeons, managers, commissioners, or GPs. This study shows that preoperative Oxford score can help inform these rationing decisions. A patient with a poorer preoperative score will gain more than a patient with a higher score, which may be seen as cost-effective. However, a

system which requires a patient to wait until they have deteriorated to a poorer score may prejudice their final outcome and increase indirect costs. The results are a reflection of the New Zealand health care system where patients are prioritized by severity. We used data from 2006 to 2010 before rationing became so severe. Oxford scores were not used to determine access during this period, and therefore, we do not believe that patients inflated their scores. Despite the lack of explicit rationing, there were relatively few patients with Oxford scores over 25 points, and the mean preoperative scores are lower than those reported in the National Joint Registry of England, Wales , Northern Ireland and the Isle of Man [29] and by other authors [8,15,18,19,25]. However, the results should be generalizable to other public health systems that are under financial pressure. Although a total joint arthroplasty may be cost-effective in patients with a preoperative Oxford score of >35 points as reported by others [18,19], there is a more limited gain in HRQoL. It is likely that, increasingly, publicly funded services will not be able to routinely offer surgery to these patients.

Strengths of this study are that we used prospectively gathered data and were able to compare the SF-6D measure with the condition-specific Oxford scores that have been widely used elsewhere. Although the OHS/OKS were not designed to be used for rationing, in practice, they have been widely used to dictate thresholds. Therefore, we believe this study is relevant to the current debate on rationing and gives some support for their use.

Limitations to this study include the observational design and the absence of comorbidity data, which may influence both preoperative and postoperative HRQoL scores. As patients did not complete an EQ-5D questionnaire, the EQ-5D-3L scores used in this study were derived from the SF-12 scores. They were calculated to enable comparisons with published studies and showed similar changes. Because the algorithm was based on UK preference weights and full cost data were unavailable, quality-adjusted life years were not calculated. The 1-year response rate of 77% is not uncommon in large observational studies but may lead to some bias. However, we found no difference in baseline variables between responders and nonresponders. The maximal benefit may occur after 12 months, so these results may not be fully representative of the maximal outcome. However, the use of 1-year data is consistent with other reports and therefore allows comparison. A longer follow-up increases the chances of other conditions developing that may impact the more general HRQoL scores.

Conclusions

Rationing for joint replacement, while unpalatable to many surgeons, is inevitable in publicly funded systems where demand exceeds capacity. This study shows that, despite not being designed for the purpose, OHS/OKS can help inform these decisions. Delaying access to a patient until they have deteriorated to a level where they have a greater gain after surgery may come at the expense of not achieving the same outcome as patients with less severe symptoms.

Conflict of interest

The authors declare there are no conflicts of interest. Dunedin Hospital receives an educational grant from DePuy Synthes to support an Arthroplasty Fellow. The authors do not believe that this has any relevance to the contents of this article.

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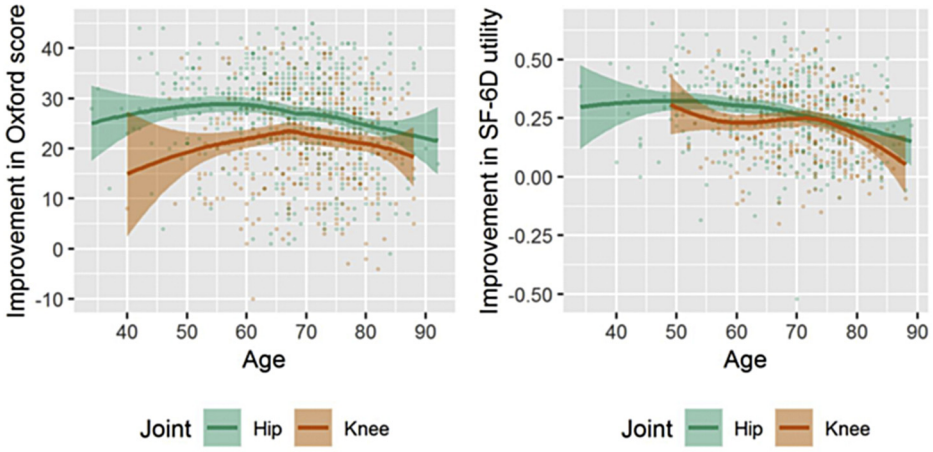

Figure A1. Improvement in Oxford score and SF-6D utility by age of the patient (unadjusted with 95% confidence intervals).

Table A1
Adjusted outcomes after joint arthroplasty surgery, by presurgery Oxford score.

Outcome measure	Presurgery Oxford score				
	<10	10-14	15-19	20-24	25+
Postoperative scores 1 y					
Oxford					
Hip	39.9 (38.5 to 41.2)	40.6 (39.4 to 41.9)	42.4 (41.0 to 43.7)[b]	42.2 (40.3 to 44.2)[a]	43.8 (41.3 to 46.4)[b]
Knee	37.1 (35.1 to 41.2) ^	37.3 (35.7 to 41.9) ^^^	38.7 (37.1 to 43.7) ^^^	39.5 (37.5 to 44.2) ^	41.7 (39.0 to 46.4)[b]
PCS					
Hip	41.7 (39.6 to 45.2)	42.5 (40.5 to 44.5)	46.5 (44.3 to 48.8)[c]	47.2 (44.3 to 50.1)[b]	46.7 (42.7 to 51.6)[a]
Knee	42.1 (38.9 to 45.2)	41.9 (39.4 to 44.5)	41.9 (39.2 to 48.8) ^^	43.5 (40.1 to 50.1)	47.5 (43.5 to 51.6)[a]
MCS					
Hip	53.0 (51.1 to 56.8)	54.8 (52.9 to 56.6)	55.1 (53.0 to 57.5)	54.3 (51.6 to 60.1)	56.3 (52.5 to 62.0)
Knee	53.9 (51.0 to 56.8)	52.9 (50.6 to 56.6)	55.1 (52.6 to 57.5)	57.0 (53.8 to 60.1)	58.2 (54.5 to 62.0)
SF-6D					
Hip	0.77 (0.74 to 0.83)	0.80 (0.77 to 0.83)	0.83 (0.79 to 0.86)[a]	0.83 (0.79 to 0.88)[a]	0.85 (0.79 to 0.94)[a]
Knee	0.78 (0.74 to 0.83)	0.78 (0.75 to 0.83)	0.79 (0.76 to 0.86)	0.83 (0.78 to 0.88)	0.88 (0.82 to 0.94)[b]
Average improvement in outcome scores after surgery					
Oxford					
Hip	33.4 (32.0 to 34.7)	28.6 (27.3 to 29.8)[c]	25.7 (24.3 to 27.1)[c]	20.5 (18.5 to 22.5)[c]	14.4 (11.8 to 17.0)[c]
Knee	29.8 (27.7 to 34.7) ^^	25.2 (23.6 to 29.8)[c] ^^	21.7 (20.1 to 27.1)[c] ^^^	17.9 (16.0 to 22.5)[c]	14.2 (11.4 to 17.0)[c]
PCS					
Hip	14.9 (12.8 to 18.0)	15.3 (13.3 to 17.3)	18.6 (16.3 to 20.9)[a]	18.3 (15.4 to 21.2)	11.5 (7.4 to 19.8)
Knee	14.9 (11.7 to 18.0)	13.8 (11.3 to 17.3)	13.7 (11.1 to 20.9) ^^	13.5 (10.1 to 21.2) ^	15.7 (11.6 to 19.8)
MCS					
Hip	17.1 (14.7 to 20.8)	12.3 (10.0 to 14.6)[b]	7.0 (4.4 to 11.2)[c]	5.7 (2.4 to 12.0)[c]	6.2 (1.6 to 10.9)[c]
Knee	17.2 (13.6 to 20.8)	10.9 (8.1 to 14.6)[b]	8.2 (5.1 to 11.2)[c]	8.1 (4.3 to 12.0)[c]	4.7 (0.0 to 10.9)[c]
SF-6D					
Hip	0.32 (0.29 to 0.37)	0.28 (0.25 to 0.31)[a]	0.26 (0.23 to 0.30)[b]	0.24 (0.20 to 0.29)[b]	0.15 (0.09 to 0.24)[c]
Knee	0.32 (0.27 to 0.37)	0.25 (0.21 to 0.31)[a]	0.22 (0.18 to 0.30)[c]	0.22 (0.17 to 0.29)[b]	0.18 (0.12 to 0.24)[c]

Adjusted outcome for the presurgery category significantly different to the reference (Oxford <10) category: [a]$P < .05$; [b]$P < .01$; [c]$P < .001$.
Adjusted outcome for the knee arthroplasty cohort significantly different to the hip arthroplasty cohort: ^$P < .05$; ^^$P < .01$; ^^^$P < .001$.
No patients with a presurgery Oxford score of 25+ had a postsurgery score <27.

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Total Hip and Knee Arthroplasties Are Highly Cost-Effective Procedures: The Importance of Duration of Follow-Up

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ABSTRACT

Background: Total hip and knee arthroplasties (THA/TKA) are clinically effective but high cost procedures. The aim of this study is to perform a cost-effectiveness analysis of THA and TKA in the New Zealand (NZ) healthcare system.
Methods: Data were collected from 713 patients undergoing THA and 520 patients undergoing TKA at our local public hospital. SF-6D utility values were obtained from participants preoperatively and 1-year postoperatively, and deaths and any revision surgeries from patient records and the New Zealand Joint Registry at minimum 8-year follow-up. A continuous-time state-transition simulation model was used to estimate costs and health gains to 15 years. Quality-adjusted life years (QALYs), treatment costs, and incremental cost-effectiveness ratios (ICERs) were calculated to determine cost effectiveness. ICERs below NZ gross domestic product (GDP; NZ$60 600) and 0.5 times GDP per capita were considered "cost effective" and "highly cost effective" respectively.
Results: Cumulative health gains were 2.8 QALYs (THA) and 2.3 QALYs (TKA) over 15 years. Cost effectiveness improved from ICERs of NZ$74,400 (THA) and NZ$93,000 (TKA) at 1 year to NZ$6000 (THA) and NZ$7500 (TKA) at 15 years. THA and TKA were cost effective after 2 years and highly cost effective after 3 years. QALY gains and cost effectiveness were greater in patients with worse preoperative functional status and younger age.
Conclusion: THA and TKA are highly cost-effective procedures over longer term horizons. Although preoperative status and age were associated with cost effectiveness, both THA and TKA remained cost effective in patients with less severe preoperative scores and older ages.

Total hip and total knee arthroplasties (THA/TKA) are clinically very effective procedures and are being performed in increasing numbers. They are high cost and high volume procedures and consume a large amount of the budget for elective orthopedic surgery. With increasing financial pressures in most healthcare systems it is important that procedures are cost effective as well as clinically effective.

Systematic reviews of the cost effectiveness of total joint arthroplasty (TJA) have concluded that THA and TKA are both highly cost-effective procedures, although noted a paucity of evidence in regard to THA [1–3]. Patients with more severe symptoms have been shown to have larger health-related quality of life (HRQoL) gains for similar costs and hence are more cost effective; however, studies have also shown lower final HRQoL for these patients, suggesting there is loss of HRQoL both before and after surgery if it is delayed due to rationing [4,5].

Nonoperative treatment of knee OA can also be clinically effective and has lower costs, so has also been shown to be cost-effective. Skou et al [6] recently concluded from randomized controlled trial data that TKA plus nonoperative treatment is not cost-effective over a 2-year horizon compared with nonoperative treatment with the option of later TKA. In contrast, a recent systematic review concluded that delaying surgery may result in short-term savings but the HRQoL losses were greater than the savings [3].

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Generic instruments such as the EQ-5D and SF-6D measure HRQoL and, in combination with utility weights, allow quality-adjusted life years (QALYs) to be calculated for cost-effectiveness analysis. Varying methods have been used to calculate QALYs at different time horizons following TJA. Some studies have collected detailed data for periods out to 2 or 5 years [6–8]. Others have used the change at 1 year in cohort studies and extrapolated over a patient's lifetime or have used hypothetical Markov modeling. A long time horizon is desirable, as the upfront cost of a TJA is high but the benefits usually last for many years. However, if an implant fails and requires revision there are further costs as well as health impacts, so it is important that long-term analysis includes revision and mortality data.

The focus of this study is publicly funded THA and TKA in the southern region of New Zealand (covering a population of approximately 330,000 people). The New Zealand healthcare system is largely publicly funded and publicly provided, although approximately 19% of total healthcare expenditure comes from private spending including private health insurance and out-of-pocket payments [9]. Patients referred for orthopedic assessment at our local public hospital are prioritised using scoring tools with the aim that the most severely affected patients are guaranteed surgery within 4 months. However, due to limited funding those who are less severely affected will be declined surgery and returned to their general practitioner for ongoing care [10,11]. This has led to poorer preoperative status than has been reported elsewhere, which would be expected to result in greater gains in HRQoL postoperatively [4]. Assuming revision and complication rates are low, we hypothesise that contemporary TJA is likely to be highly cost effective. The aim of this study is to perform a cost-effectiveness analysis for THA and TKA using local data at various time intervals to 15 years, including actual revision and mortality rates. Secondary outcomes include the effect of age, gender and preoperative status on cost effectiveness.

Methods

Data Sources

Data were collected from our departmental arthroplasty audit database on a consecutive series of 713 patients undergoing primary THA and 520 patients undergoing primary TKA at our local public hospital between January 2004 and April 2011. Follow-up surveys were completed at a median of 13 months (interquartile range 12 to 14 months) postoperatively by 565 THA patients (a completion rate of 79%) and 376 TKA patients (72%).

The New Zealand Joint Registry (NZJR) collects operative details on all primary arthroplasties performed in New Zealand and details of any subsequent revision surgery wherever performed in the country. It is mandatory for arthroplasty surgeons to participate and has 98% compliance. The local cohort was linked to NZJR data to determine any deaths or revision surgeries performed up to the end of September 2019 (ie, between 8.4 and 15.8 years of follow-up for all patients). Longer-term patient-reported Oxford Hip or Knee Scores (OHS/OKS) [12,13] are also collected by the NZJR for a random 20% sample of patients at 5 and 10 years post-surgery.

Outcome Measures

Demographic data including age and sex were collected from patient records for all participants. Patient-reported outcomes were collected pre- and postoperatively using the OHS/OKS and the SF-12 HRQoL questionnaire [14]. SF-6D health utility values were calculated from SF-12 responses to allow the calculation of QALYs for cost-effectiveness analysis [15]. As a sensitivity analysis and to compare with previous reports of cost-effectiveness of TJA, EQ-5D health utility values [16,17] were also calculated from the OHS and OKS, based on previously-published mapping algorithms [18,19].

The cost-effectiveness analysis was conducted from a payer perspective. Hospital costs, including all associated inpatient costs during the hospital stay, were calculated using public hospital cost weights published by the NZ Ministry of Health [20]. The costs of THA and TKA were $16,502 and $16,903, respectively. We assumed that non-surgical costs would be the same with and without TJA; this assumption was tested in sensitivity analyses. All costs are reported in 2018 NZ dollars (NZ$1 ≈ US$0.69 in 2018).

Preliminary Statistical Analysis

Analyses were conducted separately for the THA and TKA cohorts. We first calculated descriptive statistics for the two cohorts, including participant baseline characteristics and the patient-reported outcomes at the preoperative and postoperative time points. Summary statistics were calculated as count (percent) for discrete measures and mean (standard deviation) for continuous measures. Kaplan-Meier survival curves were calculated for both (all-cause) revision surgeries and (all-cause) mortality.

To evaluate the assumption that short-term gains from THA and TKA would be maintained over the long-term, we examined OHS/OKS scores at 5- and 10-year follow-up from the NZJR along with pre- and 1-year postoperative outcomes reported in our cohort. To check for possible selection bias, given the small proportion of participants with long-term follow-up data, outcomes were compared at each available time point between the subset of participants with complete outcome data at all time points (preoperative and 1-, 5-, and 10-years postoperative; n = 66) and the full sample of all participants with data recorded at that time point.

Cost-effectiveness Model

The cost effectiveness of THA and TKA was estimated using a continuous-time state transition model to capture the initial health gains and costs of surgery, the continued accrual of health gains over time, and the costs and health impacts of subsequent revision surgeries (Fig. C1). The model consisted of an initial simulated sample of 1000 patients, drawn by bootstrap sampling with replacement from the observed cohort; models of revision and mortality derived from the observed cohort data; trajectories of health utility values after surgery derived from the cohort data and published literature; and the costs of surgery calculated from health system cost weights.

For each individual in the simulated sample, a time-to-revision, time-to-mortality, and trajectory of health gains was drawn from the corresponding observed input parameter distributions. The cumulative health and cost outcomes of the cohort were then calculated out to each specified time horizon − 1, 2, 3, 4, 5, 10, and 15 years—and compared with outcomes for the same cohort assuming no change from baseline (representing optimised non-operative management in the observed setting) [21,22]. The model was repeated for 100 sets of randomly-drawn parameter values to derive uncertainty estimates around each outcome. Future costs and QALYs were discounted at a rate of 3.5% per annum, as recommended for cost-effectiveness analyses in NZ [23].

All analyses were conducted using *R* version 3.6.0 [24], with the 'hesim' package (v0.3.1) for health-economic simulation [25].

Estimating Inputs for the Cost-effectiveness Model

Time-to-revision, time-to-mortality, and SF-6D health utility inputs for the cost-effectiveness model were estimated from the

observed cohort data. Time-to-mortality and health utility estimates were adjusted for patients' age, sex, and preoperative OHS/OKS, to allow estimates of cost effectiveness to be derived for different patient subgroups based on these baseline variables. Time-to-revision was not adjusted for baseline covariates, as there were too few revisions observed to estimate these associations.

Time-to-revision and time-to-mortality models were estimated using survival analysis. Time-to-revision was assumed to follow an exponential distribution and time-to-mortality a log-logistic distribution, following visual inspection of the empirical survival curves and comparison of the Akaike Information Criterion for alternative models (see Appendix B).

Improvement in SF-6D health utility between baseline and 1-year follow-up was estimated using linear regression. Based on published reports of the trajectory of HRQoL gains after THA and TKA [26–30], we assumed a rapid recovery in the first 6 weeks (reaching 65% of the estimated 12-month health utility gain), followed by a slowing pace of improvement to 85% of the total gain at 3 months, 95% at 6 months, and maximal improvement at 12 months postoperatively and thereafter. Revisions were assumed to have a slower recovery reaching 90% at 6 months (and maximal improvement at 12 months).

Cost-effectiveness Analysis

The incremental per-patient QALY gains and treatment costs of TJA compared to no TJA were obtained from each simulation run, and used to calculate the incremental cost-effectiveness ratio (ICER), expressed as cost per QALY gained. Cost-effectiveness results were calculated for the entire cohort for each intervention (THA/TKA), as well as for subgroups defined by age (5-year age groups: Under 65 years, 65–69, 70–74, 75–79, 80 years and over), sex, and preoperative OHS/OKS scores (5-point bands: Under 10, 10–14, 15–19, 20–24, 25 and over).

A cost-effectiveness threshold equivalent to NZ GDP per capita (NZ$60 600 in 2018) was used, with ICERs below this threshold considered to be cost effective; we further considered ICERs below half this level ($30 300) to be highly cost effective. While there is no consensus on appropriate cost-effectiveness thresholds or how these should be determined [31], and NZ has no explicit threshold for funding decisions [32], the GDP/capita threshold has been recommended by the World Health Organisation [33,34] and is consistent with explicit and implicit thresholds in several comparable countries [35]. However, it is becoming increasingly recognised that 'opportunity cost'-based thresholds—representing the health gains foregone by funding one intervention rather than another—are generally lower than GDP-based thresholds [31,36], motivating our consideration of the lower threshold to identify more highly cost-effective scenarios. The half-GDP/capita threshold is similar to opportunity-based cost-effectiveness thresholds recently estimated for the UK [37] and Australia [38].

Sensitivity Analyses

The construction of the cost-effectiveness model and the derivation of input data required several assumptions which were tested in sensitivity analyses. First, it is recommended to consider alternative time-to-event distributions in survival analyses [39]. We therefore re-ran the cost-effectiveness simulation with alternative time-to-mortality models using several standard distributions recommended for survival models: exponential, Weibull, Gompertz, and log-normal. There were insufficient revisions observed to estimate meaningful alternative models for time-to-revision. (With very few revisions observed, the potential impact of different distributional assumptions would be negligible in any case.)

Second, we adjusted the time-to-revision models to include previously-published estimates of the relative hazard for baseline covariates (age and sex) [40,41], as there were too few revisions observed in our dataset to estimate these directly. No previous estimates were available to model the association of preoperative Oxford scores with revision rates.

For several uncertain input parameters, we conducted one-way sensitivity analyses. This involves varying these input parameters to upper and lower 'plausible' ranges, determined by review of the literature, and examining whether these plausible ranges of input values would change any of our cost-effectiveness findings. The assumption of no ongoing net costs (ie, post-surgery costs the same as ongoing nonoperative management costs) was varied to include ongoing costs of $500 per year for post-surgery care or nonoperative management costs of $500 per year (ie, an ongoing net cost saving for surgery), based on experience from an optimised nonoperative management pathway [42]. The assumption that health utility values would remain constant at baseline levels, on average, for the nonoperative management group was varied to account for either regression to the mean in patient outcomes (potentially accounting for some of the improvement in outcomes observed in the TJA cohort) [43] or further deterioration in health status over time, at an average rate of 0.03 (on the 0–1 utility scale) per year. The recovery trajectory of health utility values over the first year post-surgery was varied to be either faster than our base case assumption (rapid recovery to achieve 85% of the health gain by 6 weeks, and the remainder by 6 months) or slower (90% of the health gain reached gradually by 6 months, with the remainder by 1 year). As no data were available on surgical complications or readmissions for our cohort, we used previously published estimates of readmission rates in our local system [44] to evaluate the potential impact on costs and cost-effectiveness of TJA. No data on the cost of readmissions were available; we assumed a cost of $20,000 per readmission for our sensitivity analysis. Lastly, the discount rate applied to future costs and health gains was varied to 0% and 5% per year, as has been recommended for cost-effectiveness analyses in NZ [23].

Results

Descriptive Analysis

Demographic characteristics and patient-reported outcome scores are shown in Table 1. THA patients were slightly younger, on average, than TKA patients. The majority of both cohorts were female. Baseline patient-reported outcome scores were poor, and slightly worse on all scores for THA compared to TKA patients. All outcome scores showed clinically and statistically significant improvements at 1-year follow-up.

Postoperative health gains, as measured by OHS and OKS, persisted with very little change (on average) through both 5- and 10-year follow-up (Fig. A1). There were no meaningful differences at any time point between the subsample of participants with complete follow-up data to 10 years and the full sample of all participants at each follow-up point, suggesting that those with long-term follow-up were a representative sample of the cohort (at least with respect to OHS and OKS) and selection bias is unlikely to be an issue in evaluating long-term health gains (Fig. A2).

Over the observed follow-up period, 13 THA and 5 TKA patients underwent revision surgery. Revision-free rates at 15 years were 97.0% (95% CI: 95.2 to 98.8) for THA and 98.1% (96.3 to 99.8) for TKA (Fig. 1A).

At the date of final follow-up (September 2019), 105 THA patients and 81 TKA patients had died. The 15-year survival rates were 77.4% (95% CI: 73.3 to 81.8) for THA patients and 74.6% (69.6 to 80.0) for TKA patients (Fig. 1B).

Table 1
Baseline Characteristics and Patient-Reported Outcome Scores.

Patient Characteristic	THA	TKA
Age; mean(SD)	68.1 (11.0)	70.9 (8.8)
Gender; n(%)		
Male	254 (45%)	151 (40%)
Female	311 (55%)	224 (60%)
Patient-reported health outcomes; mean(SD)		
Oxford Score		
Preoperative baseline	14.0 (6.6)	15.6 (6.1)
Postoperative follow-up	40.7 (7.3)	37.4 (8.2)
Change (95% CI)	26.8 (26.0 to 27.6)	21.8 (20.9 to 22.8)
SF-12 PCS score		
Preoperative baseline	28.1 (5.4)	28.3 (5.3)
Postoperative follow-up	43.5 (11.0)	41.3 (10.4)
Change (95% CI)	15.4 (14.3 to 16.4)	13.0 (11.7 to 14.3)
SF-12 MCS score		
Preoperative baseline	43.1 (12.0)	44.7 (11.4)
Postoperative follow-up	54.5 (9.4)	53.8 (9.6)
Change (95% CI)	11.4 (10.2 to 12.6)	9.2 (7.7 to 10.6)
SF-6D utility		
Preoperative baseline	0.53 (0.11)	0.56 (0.10)
Postoperative follow-up	0.80 (0.15)	0.77 (0.15)
Change (95% CI)	0.27 (0.25 to 0.29)	0.22 (0.20 to 0.24)
EQ-5D utility[a]		
Preoperative baseline	0.24	0.31
Postoperative follow-up	0.83	0.80
Change (95% CI)	0.59 (0.55 to 0.64)	0.49 (0.46 to 0.52)

SD, standard deviation; CI, confidence interval; PCS, SF-12 Physical Component Summary score; MCS, SF-12 Mental Component Summary score; THA, total hip arthroplasty; TKA, total knee arthroplasty.
[a] EQ-5D scores are calculated from group mean Oxford scores; individual-level EQ-5D values are not available to calculate SDs.

Model Inputs

Modeled revision rates, from the survival model, were close to observed rates over the 15-year period, although uncertainty intervals were wide, particularly for TKA patients, due to the small number of observed revisions (Fig. A3).

HRQoL gains were smaller for older patients and for patients with better preoperative OHS and OKS scores, for both THA and TKA (Table C1). There was no significant difference in HRQoL gains between men and women for either procedure.

All model input parameters and distributions are reported in the Appendix (Tables C1-C3).

Cost-effectiveness Findings

Cumulative health gains increased steadily over the modeled time period, reaching 2.8 QALYs (95% uncertainty interval: 2.7 to 3.0) per THA patient and 2.2 QALYs (2.1 to 2.4) per TKA patient over 15 years (Fig. 2A). Surgery costs were high in the first year ($16 549 for THA; $16 931 for TKA), but cumulative costs increased only

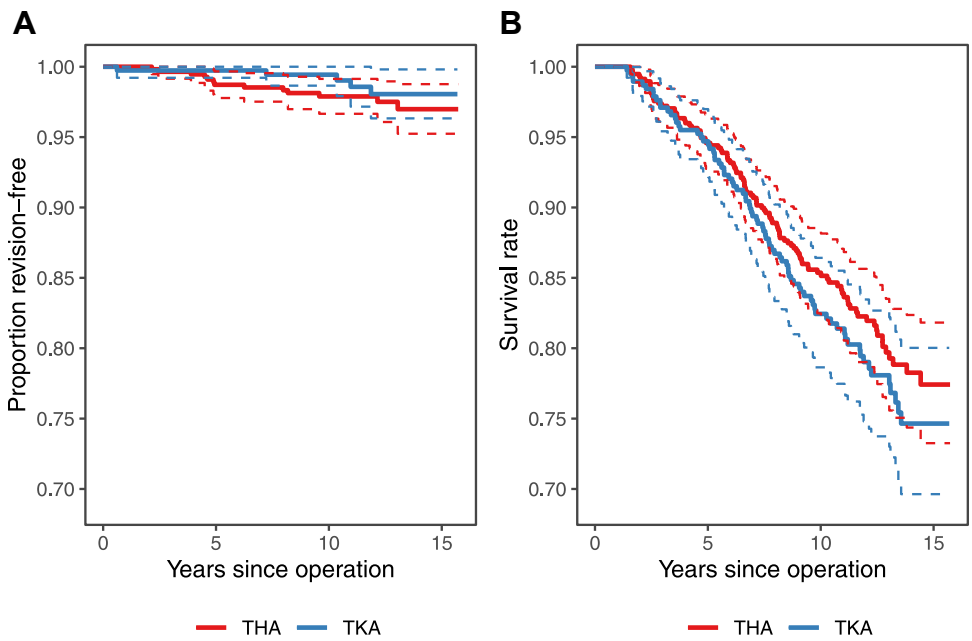

Fig. 1. Revision and mortality rates. (A) Revision-free survival rates, censored at the time of death or final follow-up (September 2019). (B) Survival rate, censored at the time of final follow-up (September 2019). THA, total hip arthroplasty; TKA, total knee arthroplasty.

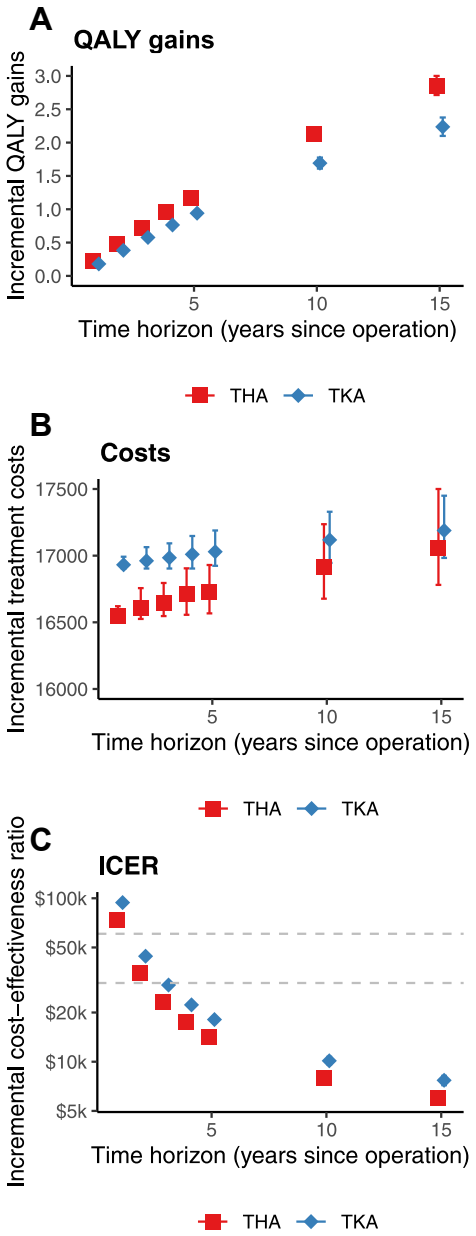

Fig. 2. Cumulative QALY gains (A), costs (B), and incremental cost-effectiveness ratios (C), THA and TKA. Dashed lines in panel C indicate the 0.5-times and 1-times GDP/capita willingness-to-pay thresholds; all points below these lines are considered cost effective at the corresponding level. GDP, gross domestic product; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life years; THA, total hip arthroplasty; TKA, total knee arthroplasty.

slightly over longer time horizons due to low rates of revision (Fig. 2B). The projected cost effectiveness therefore improved throughout the modeled time period (Fig. 2C).

Neither THA nor TKA were cost effective over a 1-year horizon (ICER = $73 900 for THA; $94 100 for TKA), due to the high up-front costs of surgery. Both were cost effective over a 2-year horizon and highly cost effective over a 3-year and longer time horizon. Over 15 years, ICERs were $6 000 for THA and $7 700 for TKA.

Using the EQ-5D values derived from Oxford scores, there were QALY gains of 0.49 at 1 year and 6.21 at 15 years for hips, and 0.40 at 1 year and 4.99 at 15 years for knees (Fig. A4, Panel A). The ICERs ranged from $33 500 at 1 year to $2 700 at 15 years for THA and $42 000 at 1 year to $3 500 at 15 years for TKA (Fig. A4, Panel C), and were therefore considered cost effective over all time horizons (and highly cost effective after 2 years).

Sub-group Analyses

QALY gains and cost effectiveness were greater in patients with worse preoperative OHS and OKS scores and younger age, for both THA and TKA, while there was little difference in any outcomes between men and women (Fig. 3; Figs. A5 and A6).

Sensitivity Analyses

Alternative parametric models for time-to-mortality made very little difference to any of the results (Fig. A7); nor did adjusting revision risk for baseline patient characteristics (Fig. A8).

The results of the one-way sensitivity analyses are presented in the tornado plots in Figure 4. Over a 1-year horizon (Panel A), the assumptions with the largest potential impact on estimated cost effectiveness were the extent of possible regression to the mean in health utility for patients continuing to be managed nonoperatively and the short-term recovery trajectory of health utility following TJA. None of the one-way sensitivity analyses changed the main findings over a 1-year horizon.

Over the medium-term 3-year horizon (Panel B), the largest potential impacts on cost effectiveness came from regression to the mean in health utility for nonoperative management. Both THA and TKA remained cost effective in all analyses at the 3-year horizon, with THA highly cost effective in all scenarios except regression to the mean in nonoperative health utility.

Over the long-term 15-year horizon (Panel C), ongoing treatment costs and nonoperative health utility trajectories had the largest impacts on cost effectiveness, but both THA and TKA remained highly cost effective in all scenarios.

Discussion

The cost effectiveness of THA and TKA improves rapidly over longer follow-up. We found that THA and TKA are cost effective after 2 years and highly cost effective after 3 years. THA was more cost effective than TKA, due to larger health gains for similar costs. Greater health gains and improved cost effectiveness were seen in younger patients and those with poorer preoperative Oxford hip or knee scores.

The average SF-6D scores at 12 months for THA (0.80; change +0.27) and TKA (0.77; +0.22) were consistent with other studies using the SF-6D, which have reported scores ranging from 0.72 to 0.799 (THA) and 0.71 to 0.80 (TKA), and gain in scores from 0.168 to 0.185 (THA) and 0.114 to 0.15 (TKA) [7,26,27,30,45,46]. Greater gains in the current study were due to poorer preoperative scores in our patients.

These greater HRQoL gains were also seen in our long-term QALY estimates compared to other studies. Previous studies have reported longer-term (15 years to lifetime) health gains of 1.39 to 2.35 QALYs after THA and 1.34 to 2.144 QALYs after TKA [26,27,46]. Our gains were 2.8 QALYs (THA) and 2.3 QALYs (TKA) over 15 years. Patient survival in our models was 78% for THA patients and 75% for TKA patients suggesting that the 15-year horizon we used underestimates total lifetime QALY gains.

Elmallah et al. calculated an ICER at 1 year of US$39 453/QALY for THA and US$43 107/QALY for TKA, although it is unclear how they derived these figures. [27]. It appears from their reported QALYs and costs that 1-year ICERs should be US$101 000 and US$119 000 respectively. Our ICER at 1 year was $73 900 (≈US$51 000) for THA and $94 100 (≈US$64 900) for TKA.

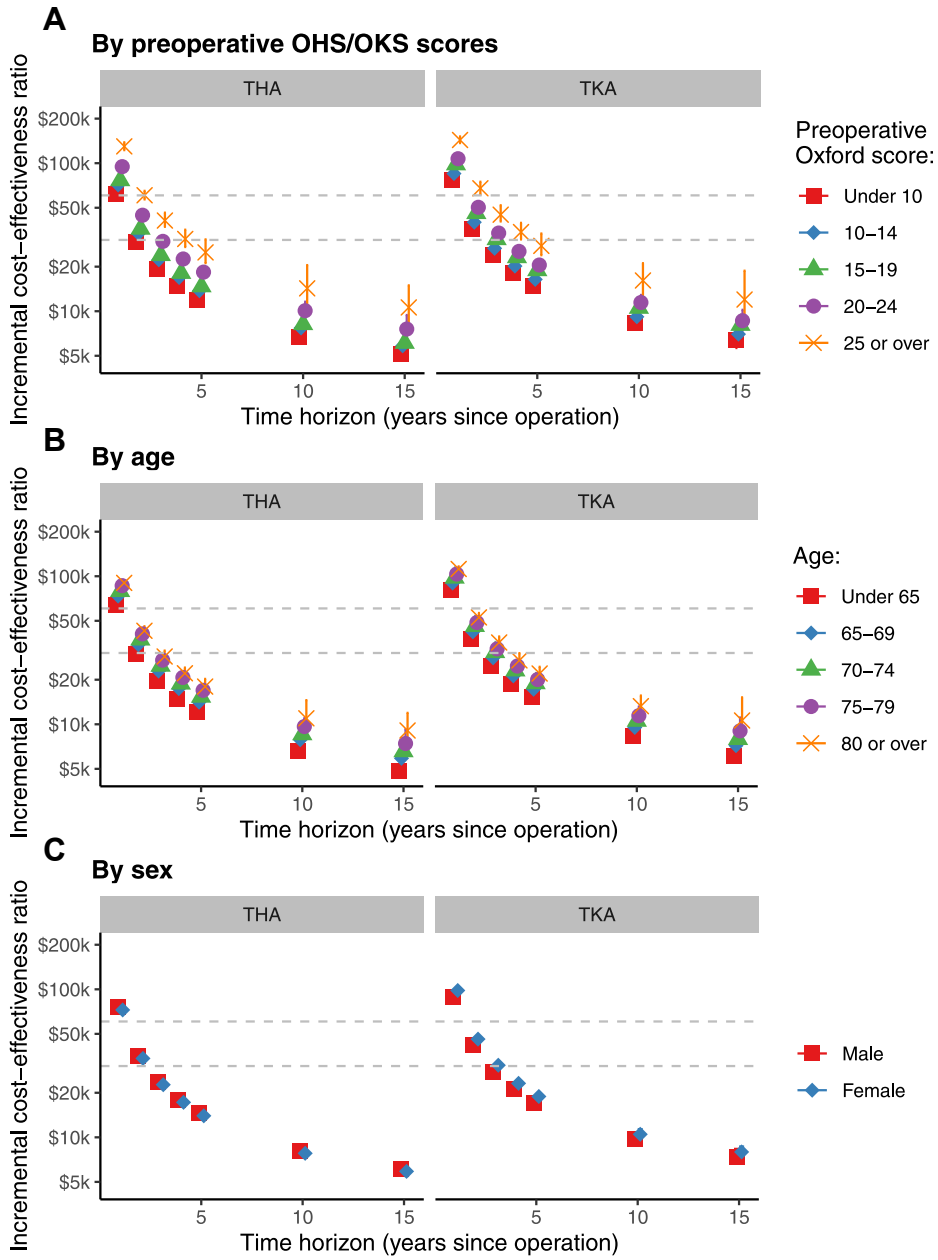

Fig. 3. Cost-effectiveness ratios for THA and TKA, by baseline covariates. Dashed lines indicate the 0.5- and 1-times GDP/capita willingness-to-pay thresholds; all points below these lines are considered cost effective at the corresponding level. GDP, Gross domestic product; OHS, Oxford Hip Score; OKS, Oxford Knee Score; QALY, quality-adjusted life years; THA, total hip arthroplasty; TKA, total knee arthroplasty.

Fordham et al. reported an ICER at 5 years of £7 182 for Exeter THA [7], consistent with our 5-year ICER of $14 200 (≈£7 400) for THA.

Other studies have used the EQ-5D to calculate QALY gains from TJA. The EQ-5D has approximately twice the range of utility values of the SF-6D and therefore gives a higher estimate of health utility gains. In published studies, these range from 0.358 to 0.470 following THA and from 0.267 to 0.332 following TKA [5,8,47,48]. In order to compare our results with these reports, we mapped OHS and OKS to EQ-5D utility values and found utility gains of 0.59 after THA and 0.49 after TKA, with 15-year gains of 6.2 QALYs for THA and 5.0 QALYs for TKA. These gains were greater than those previously reported, due to worse preoperative status in our patients; the use of mapping algorithms to estimate EQ-5D utility values in our study may also have introduced uncertainty in comparisons with previous studies. Jenkins et al. calculated lifetime cost/QALY, using a discount rate of 3.5%, of £2 852 (THA) and £3 738 (TKA) [47]. At 15 years, using the same utility instrument and discount rate, our ICER was $2 700 (≈£1 400) for THA and $3 500 (≈£1 800) for TKA. In the KAT trial, Dakin et al. reported an ICER of £5 623/QALY [8]. Our comparable ICER at 5 years was $8 100 (≈£4 200) for TKA. All of these estimates are well within the highly cost-effective range.

Similar to other studies, we showed greater gains in HRQoL in younger patients [7,45]. This was evident at 1 year, indicating that the gains were independent of mortality, but became greater over the 15-year horizon as a larger proportion of older patients died. We saw no difference in gains by gender.

It has previously been shown that 1-year outcome scores are worse in patients with worse preoperative Oxford scores, but they

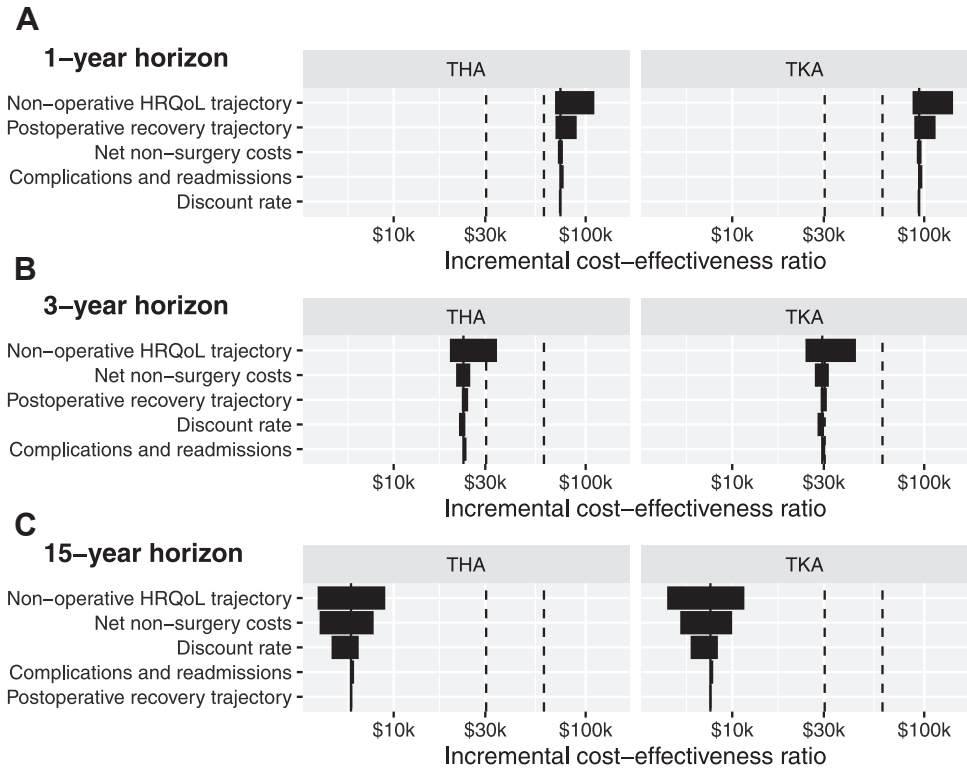

Fig. 4. "Tornado plot" of one-way sensitivity analyses on key model input parameters/assumptions. Bars show the range of estimated ICERs when varying assumptions on input parameters to their most favorable (lowest ICER estimate) and least favorable (highest ICER estimate) "plausible" values, one-at-a-time. For parameter ranges considered, see 'Sensitivity analyses' in the Methods in the text. Dashed lines indicate the 0.5- and 1-times GDP/capita willingness-to-pay thresholds; solid vertical line indicates the ICER from primary analyses. GDP, Gross domestic product; HRQoL, health-related quality of life; THA, total hip arthroplasty; TKA, total knee arthroplasty.

receive the greatest gains postoperatively [4]. Eibich et al. found that the preoperative Oxford score was systematically associated with costs and quality of life, with increased costs for patients with poorer preoperative scores [5]. From US cohort data, Ferket et al. found a mean increase in SF-6D of only 0.008 after TKA and concluded that there were minimal gains in health utility in patients with good physical function as determined by the SF-12 PCS [49]. They calculated that, at a threshold of US$100 000/QALY, TKA was only cost effective if performed on patients with significant loss of function indicated by a preoperative SF-12 PCS below 20 points. In contrast, Dakin et al. concluded that while the benefits varied with preoperative OKS, TKA was cost effective even in patients with a preoperative OKS over 35 or 40 depending on ASA status [8]. In our study, TKA was cost effective in patients with preoperative OKS over 25 points after 3 years and highly cost effective after 5 years.

A systematic review found that non-operative treatment involving exercise interventions was cost-saving [50]. The Management of Osteoarthritis (MOA) trial showed gains in QALYs of 0.19 at 2 years with exercise therapy over usual care, and lower total health system costs [51]. Skou et al [6] found that providing TKA in addition to non-surgical treatment resulted in greater health utility compared with non-surgical treatment only, but did not find it to be cost-effective at the 2 year horizon. In their study the addition of non-surgical treatment and a high reoperation and complication rate increased the cost of the TKA group, while 32% of the non-surgical group had a subsequent TKA. They noted the need for studies with a longer time horizon but questioned whether the results of TKA would be maintained at longer follow-up. Our study and the NZJR data suggest that these gains are maintained to at least 10 years, resulting in improving cost effectiveness over time. However, we have assumed no QALY gain from non-operative treatment in our model, as evidence suggests that even with a coordinated multidisciplinary approach there is no significant improvement in this setting over both short- and longer-term follow-up to 5 years [21,22].

In New Zealand the costs of publicly-funded THA and TKA ($16,502 and $16,903) are relatively high compared with other common orthopedic procedures such as knee arthroscopy ($5743) and rotator cuff repair ($7154), although they are lower than for spinal decompression and fusion (one-level) ($27,631) and total ankle replacement ($21,620) [20]. Comparative data on the cost-effectiveness of these procedures are not available. In an environment where health systems have limited resources, similar data on the cost-effectiveness of other procedures both within orthopedics and across other specialties should be considered to aid prioritisation and rationing decisions.

Strengths of this study are that this is a reasonably large prospectively-gathered dataset that includes all revision procedures performed anywhere in NZ. Our modeling is consistent with the observed data and we believe gives a generalisable estimate of cost effectiveness in a population with poor preoperative status. Unlike other studies we have not extrapolated to lifetime gains. Our results are consistent with previous work, with differing outcomes likely attributable to poorer baseline scores—meaning that postoperative gains were greater without a major difference in provision costs [4,5]. We have included real revision rates and factored in the costs of revision surgery whereas other studies have not included revision surgery or used an estimate.

We assumed that the majority of the improvement occurs within the first 6 weeks, meaning greater health utility gains in the first year than if an average of the gain at 12 months is used. Conversely, we did not assume that the full utility gain accrued for

the whole of the first year (and thereafter) as some authors have done. We used SF-6D as our primary health utility measure rather than EQ-5D as this can be directly derived from the SF-12 data we collected prospectively.

Limitations of the study are that we had incomplete follow-up scores at 12 months and only 20% of the cohort were sampled by the NZJR at 5 and 10 years. However, we found no differences between those sampled and the remainder of the group. There was wide uncertainty in revision rates by 15 years postoperatively due to the small number of observed revisions (especially for TKA); however, the very low number of observed revisions means that even (proportionally) wide confidence intervals had little impact on our cost-effectiveness findings. We did not collect complication data including readmissions which would have increased health care costs. We did not collect EQ-5D so used published algorithms to convert OHS/OKS into EQ-5D for secondary analyses to allow comparison with other studies.

Our modeling assumes no change in health utility state with non-operative treatment over the 15-year horizon. While there may have been some small gains with non-operative treatment many will have deteriorated therefore we consider our results a conservative estimate of the net gains from surgery. We also included only direct hospital costs and did not include GP visits, drug costs or other societal costs which are likely to be greater in patients treated non-operatively [22]. We had relatively few patients with milder preoperative scores, but TJA was cost effective even in these patients. We also had a pleasingly low revision rate which may be not be representative of outcomes elsewhere, potentially limiting generalisability.

Conclusion

We have shown that both THA and TKA are cost-effective procedures after 2 years and highly cost effective from 3 years onwards, with decreasing ICERs with longer follow-up. THA was consistently more cost effective than TKA at every time point. While preoperative status had the strongest influence on cost effectiveness, THA and TKA remained cost effective in those with less severe preoperative scores, but only became highly cost effective at 4-5 years. Similarly the procedures were also highly cost effective in older patients after 3-4 years.

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Appendix

Appendix A. Supplementary Results

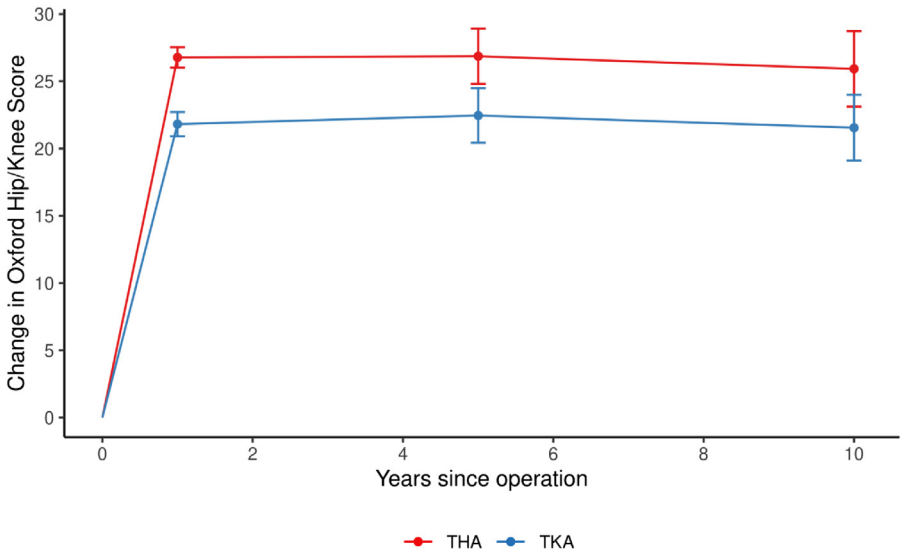

Figure A1. Change in Oxford Hip and Knee Scores from preoperative baseline, at 1-, 5-, and 10-year follow-up. Error bars show 95% confidence intervals. All available observations used at each time point (THA: n = 542 at 1-year follow-up, n = 58 at 5-year follow-up, and n = 29 at 10-year follow-up; TKA: n = 371, n = 58, and n = 38, respectively); see Figure A2 for evaluation of potential selection bias at 5- and 10-year follow-up. THA, total hip arthroplasty; TKA, total knee arthroplasty.

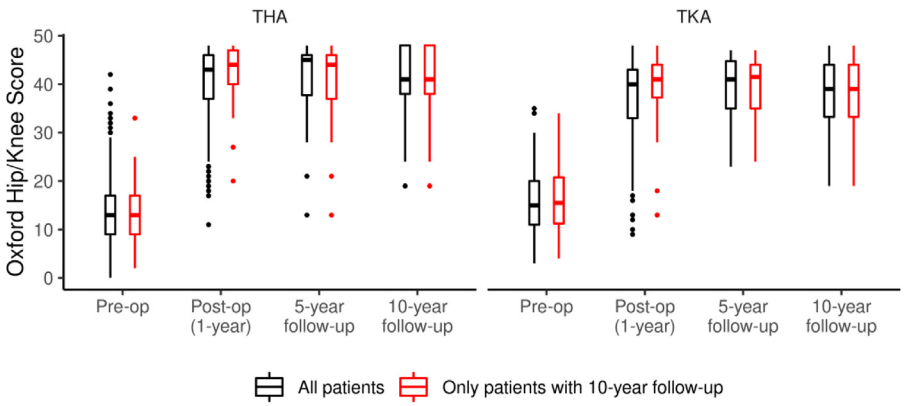

Figure A2. Oxford Hip and Knee Scores, preoperative baseline to 10-year follow-up, by follow-up completion status. THA, total hip arthroplasty; TKA, total knee arthroplasty.

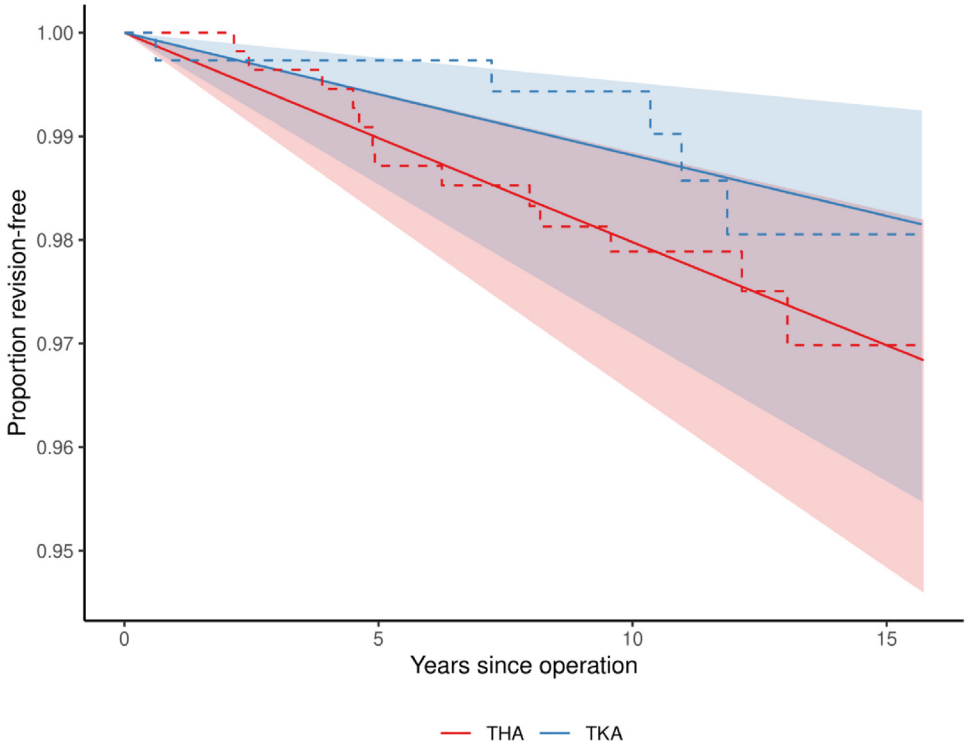

Figure A3. Revision-free survival rates, modeled and observed. THA, total hip arthroplasty; TKA, total knee arthroplasty.

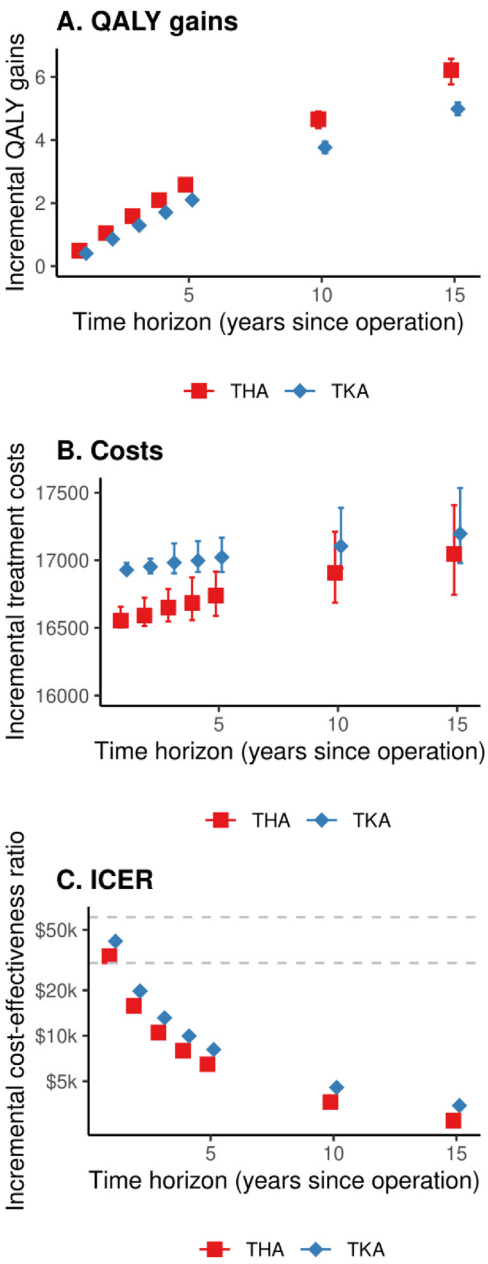

Figure A4. Cumulative QALY gains, costs, and incremental cost-effectiveness ratios, THA and TKA, using EQ-5D utility values mapped from Oxford hip and knee scores, Dashed lines in Panel C indicate the 0.5- and 1-times GDP/capita willingness-to-pay thresholds; all points below these lines are considered cost effective at the corresponding level. GDP, gross domestic product; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life years; THA, total hip arthroplasty; TKA, total knee arthroplasty.

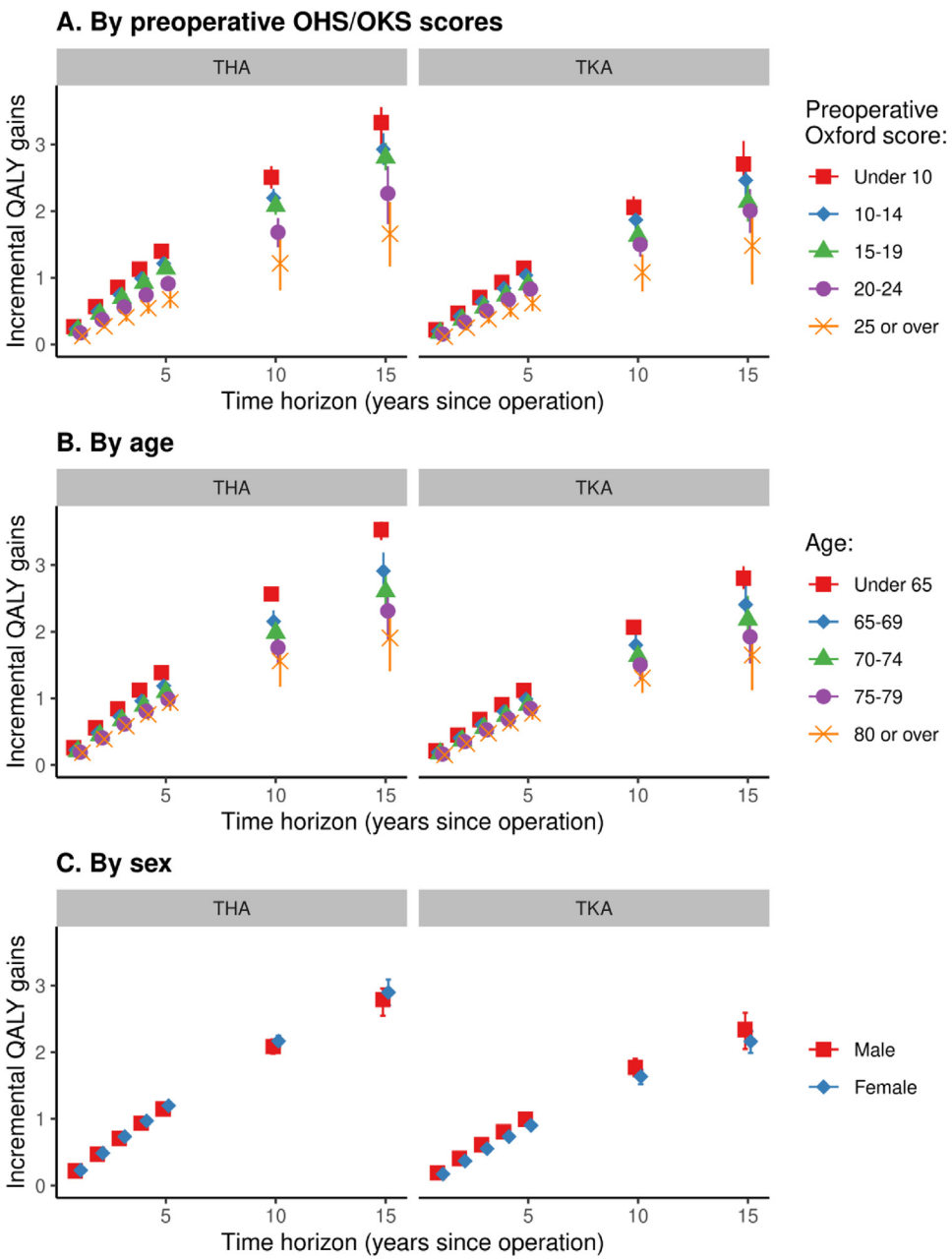

Figure A5. Cumulative QALY gains following THA and TKA, by baseline covariates. OHS, Oxford Hip Score; OKS, Oxford Knee Score; QALY, quality-adjusted life years; THA, total hip arthroplasty; TKA, total knee arthroplasty.

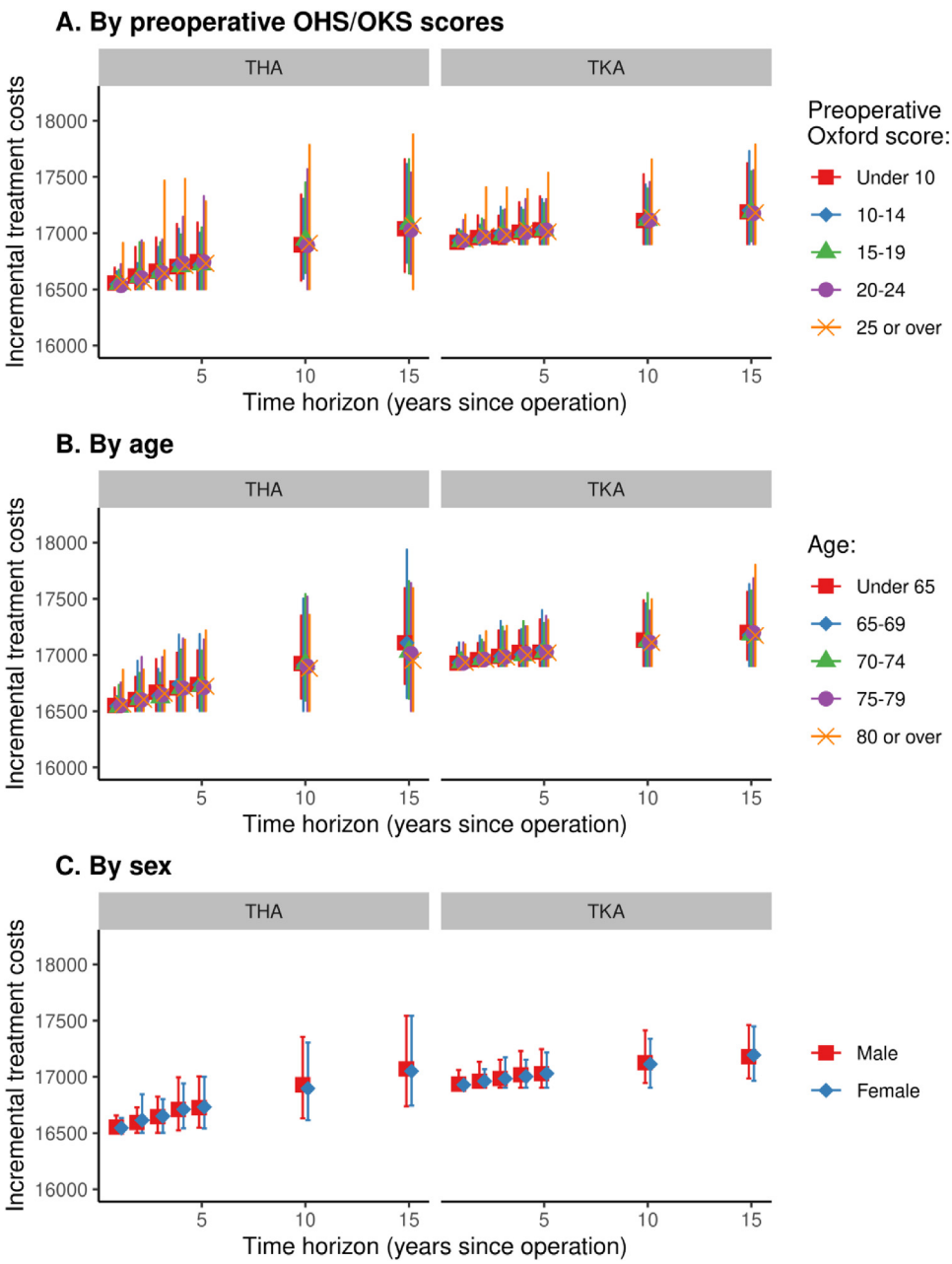

Figure A6. Cumulative surgery costs (incl. revisions) for THA and TKA, by baseline covariates. OHS, Oxford Hip Score; OKS, Oxford Knee Score; THA, total hip arthroplasty; TKA, total knee arthroplasty.

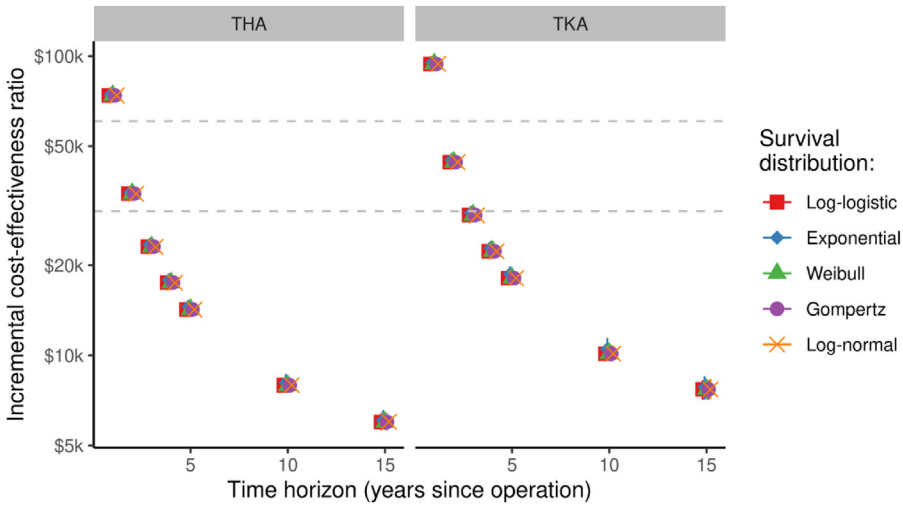

Figure A7. Cost-effectiveness ratios for THA and TKA, under different assumptions on survival distributions. Dashed lines indicate the 0.5- and 1-times GDP/capita willingness-to-pay thresholds; all points below these lines are considered cost effective at the corresponding level. GDP, gross domestic product; THA, total hip arthroplasty; TKA, total knee arthroplasty.

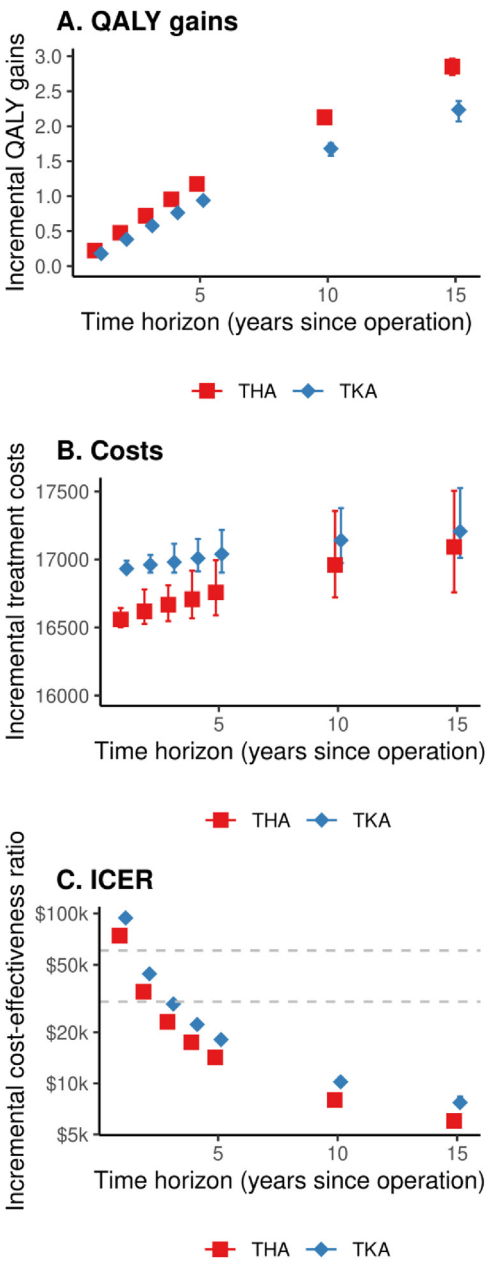

Figure A8. Cost-effectiveness ratios for THA and TKA, with revision rates adjusted for baseline patient characteristics. Dashed lines in Panel C indicate the 0.5- and 1-times GDP/capita willingness-to-pay thresholds; all points below these lines are considered cost effective at the corresponding level. GDP, gross domestic product; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life years; THA, total hip arthroplasty; TKA, total knee arthroplasty.

Appendix B: Survival Distribution Preliminary Modeling

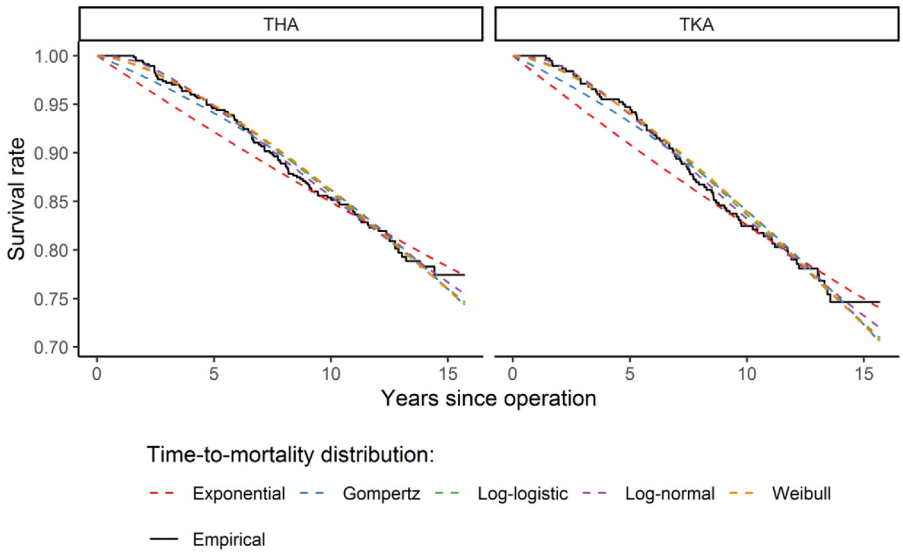

Figure B1. Empirical and fitted survival curves, time-to-mortality. THA: Total hip arthroplasty; TKA: Total knee arthroplasty.

Table B1
AIC Values for Different Fitted Survival Curves, Time-To-Mortality.

Distribution	THA	TKA
Exponential	945.7	762.2
Gompertz	933.8	755.4
Log-logistic	919.8	746.3
Log-normal	919.6	746.7
Weibull	923.2	748.0

AIC, Akaike's Information Criterion; THA, total hip arthroplasty; TKA, total knee arthroplasty.

The empirical survival curves and the fitted distributions for alternative time-to-mortality distributions were examined to determine the preferred distribution for survival modeling. All fitted distributions except the exponential distribution fit the observed survival curves closely, with little difference between the log-logistic, log-normal, and Weibull distribution fitted curves (Figure B1).

Akaike's Information Criterion (AIC) was compared between models to find the optimal model (with lower AIC values indicating a 'better' model for the observed data). The AIC values were lowest for the log-logistic and log-normal models for both THA and TKA, with very little difference between these two (Table B1).

There were insufficient data to estimate alternative survival distributions for revision-free survival, with only 13 THA and 5 TKA revisions observed over the 15-year follow-up period. Given these very small numbers of revisions, we considered the likely impact of alternative survival distributions on cost-effectiveness results to be negligible.

Appendix C: Model Input Parameters

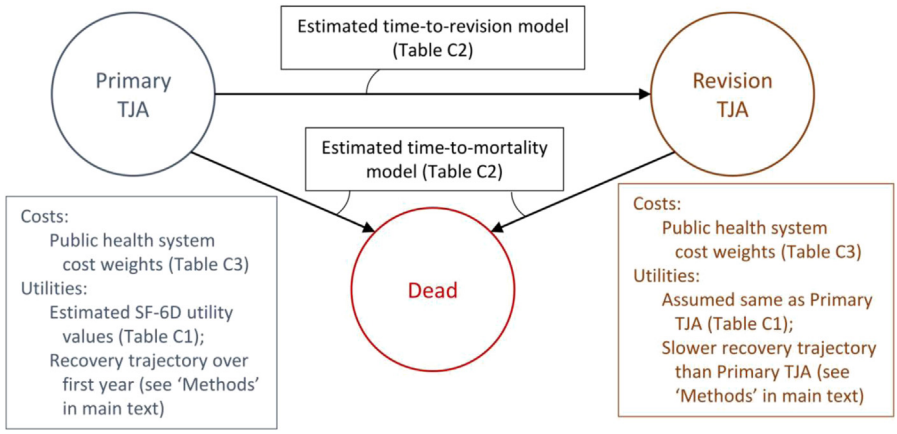

Figure C1. State-transition model structure. All patients start in state 'Primary TJA' and may progress to 'Revision TJA' and/or 'Dead' based on individual time-to-event simulation (derived from observed survival rates). Costs and utilities are accrued to the specified time horizon (1, 2, 3, 4, 5, 10, or 15 years), with a discount rate of 3.5% per year. Input parameters are derived and the simulation model is run separately for THA and TKA. TJA, total joint arthroplasty; THA, total hip arthroplasty; TKA, total knee arthroplasty.

Table C1
Gain in SF-6D Health Utility Scores.

Variable	THA	TKA
Constant	0.586 (0.054)	0.512 (0.079)
Age (years)	−0.00343 (0.00077)	−0.00257 (0.00107)
Sex (female)	0.014 (0.016)	−0.021 (0.018)
Oxford score	−0.00655 (0.00118)	−0.00626 (0.00140)

Cells report coefficients (std. error) from the regression models for change in SF-6D health utility values ($SF-6D_{Post-operative} - SF-6D_{Pre-operative}$).
THA, total hip arthroplasty; TKA, total knee arthroplasty.

Table C2
Time-To-Revision and Time-To-Mortality Survival Models.

Variable/Parameter	THA	TKA
Exponential time-to-revision model:		
Rate	0.00204 (0.00119 to 0.00352)	0.00119 (0.00049 to 0.00286)
Log-logistic time-to-mortality model:		
Shape	1.84 (1.54 to 2.20)	1.75 (1.43 to 2.14)
Scale	1 527 (379 to 6 161)	1 001 (179 to 5 599)
Age (years)	0.940 (0.923 to 0.958)	0.948 (0.928 to 0.969)
Sex (female)	1.255 (0.966 to 1.629)	1.195 (0.887 to 1.611)
Oxford score	1.020 (0.999 to 1.041)	1.007 (0.983 to 1.032)

Cells report (exponentiated) coefficients (95% confidence interval) of the time-to-revision and time-to-mortality survival models. Time-to-revision censored at death.
THA, total hip arthroplasty; TKA, total knee arthroplasty.

Table C3
Surgery Costs.

Procedure	THA	TKA
Primary TJA	$16 502	$16 903
Revision TJA	$23 876	$22 156

Cells report mean surgery costs (weighted average of procedures coded as with and without serious complications). Surgery costs were treated as fixed (no stochastic parameter distribution).
TJA, total joint arthroplasty; THA, total hip arthroplasty; TKA, total knee arthroplasty.

Chapter 6

Improving perioperative management.

Perioperative management of patients is constantly evolving and improving. It is driven both by a desire for quality but also the need for beds and cost saving. In an early paper '*Clinical pathways in total knee arthroplasty: a New Zealand Experience'* we reported on the introduction of clinical pathways in 1997 to help streamline care. It showed a reduction in length of stay (LOS) from 12.9 days to 10.3 days without an increase in complications or readmissions. More recently, there has been significant interest in enhanced recovery programmes in joint replacement. [1] I was fortunate to attend a presentation by Tom Wainwright and Mr Rob Middleton Middleton in 2012 on enhanced recovery techniques as used in Bournemouth, UK. Ward staff including the Charge Nurse and lead physiotherapist also attended. We were inspired and introduced many of their techniques as part of the Orthopaedic Patient Pathway. '*Enhanced recovery after surgery for hip and knee replacements'* reports on our experience and showed a decrease in LOS, no increased risk of complications and 98% discharged home. This was despite the fact that the mean Body Mass Index (BMI) was over 30 and the proportion of sick and very sick patients (American Association of Anaesthesiologists (ASA) grade 3 and 4) increased from 23% to 32%.

Sicker patients have led to an increased interest in perioperative medicine. Cardiopulmonary exercise testing (CPET) is a relatively new technique to assess a patient's fitness for surgery. An issue with patients with lower limb disease is that conventional treadmill testing may not be possible. Our paper '*Cardiopulmonary exercise testing in severe osteoarthritis: A crossover comparison of four exercise modalities'* compares different exercise modalities in patients with hip and knee OA. It concludes that arm ergometry is not an appropriate substitute for CPET modalities utilising the lower limbs in patients affected by osteoarthritis as it underestimates peak $\dot{V}O_2$ and anaerobic threshold.

Complications are an important cause of morbidity and potential costly returns to theatre. Intraoperative imaging can play an important role in avoiding complications during surgery but has the potential to be hazardous to both patient and surgeon. It is commonly used in fracture management including hip fractures.

Our first study *'Radiation use in the orthopaedic theatre: a prospective study'* audited the use of radiation, predominantly in the trauma theatre. It highlighted the increased radiation exposure to the patient from taking hard copy films with the image intensifier and the potential hazards to junior staff from catching their hands in the beam.
In elective surgery an important use is to aid in the placement of pedicle screws during instrumented spinal surgery. Malposition can lead to nerve irritation and damage, or loss of fixation. Imaging also helps to prevent wrong level surgery. Our study *'Radiation exposure during fluoroscopically assisted pedicle screw insertion in the lumbar spine'* has become a standard with 104 citations.

Reference

1. Wainwright, T., Middleton, R. (2010). An orthopaedic enhanced recovery pathway. Current Anaesthesia and Critical Care, 114-20.

Journal of Orthopaedic Surgery 2003: 11(2): 166–173

Clinical pathways in total knee arthroplasty: A New Zealand experience

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ABSTRACT

Purpose. To ascertain the effects of a clinical pathway in our institution.
Methods. This retrospective and comparative study was performed on all patients undergoing total knee arthroplasty over a 5-year period. This period covered the 30 months prior to the introduction of the pathway (group 1), and the 30 months following its introduction (group 2).
Results. There was a significant reduction in the duration of hospital stay of group 2 patients ($p<0.0001$), with 62.8% of these patients staying less than 8 postoperative days. There was a reduction in the number of patients with thromboembolic complications ($p<0.05$) and no increase in overall complications or readmission rate. There was a trend to increased use of rehabilitation services among group 2 patients.
Conclusion. Clinical pathway implementation resulted in a significant reduction in the length of stay, and achieved a more efficient management of hospitalised patients without compromising outcome.

Key words: *arthroplasty; clinical pathway; complications; length of stay; managed care; patient readmissions*

INTRODUCTION

Total knee arthroplasty (TKA) is performed at an increasing rate as a result of the increase of the mean age of the population. The number of primary TKAs performed in New Zealand during the year 2000 had a 23% increase compared with the previous year.[1] Such an increase drains the time and financial resources of the health care providers. Clinical pathways have been introduced in North America, Australia, and the UK, with the expectation of

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maintaining a high quality of care at a lower cost. Clinical pathways are standardised protocols for the management of patients with common conditions or those undergoing common surgical procedures. They are intended to cover all foreseeable aspects of care by all members of the health care team managing the involved patients. The objectives of implementing the protocols include the standardisation of care and the reduction of in-patient stay and cost without adverse effect on patient outcomes. In the literature there is evidence that the use of clinical pathways help reduce the length of stay (LOS)[2–9] and cost[4,6,8,10] without undesirable outcomes.[3,6,11] Most studies also show that after the implementation of a pathway, there is no significant change in postoperative complication and readmission rate.[3,4,7] We report our experience with a clinical pathway for TKA in a New Zealand public hospital.

METHODS

In July 1997 we introduced a clinical pathway for patients undergoing TKA. The pathway was developed by a multidisciplinary team of health care workers involved in the care of TKA patients. The team comprised an orthopaedic surgeon, the clinical care pathway coordinator, senior nursing staff, and

Total Knee Replacement Clinical Care Pathway

Patient Label

Day 2, DATE / /	C	Comment	*	Variation	/	N/A

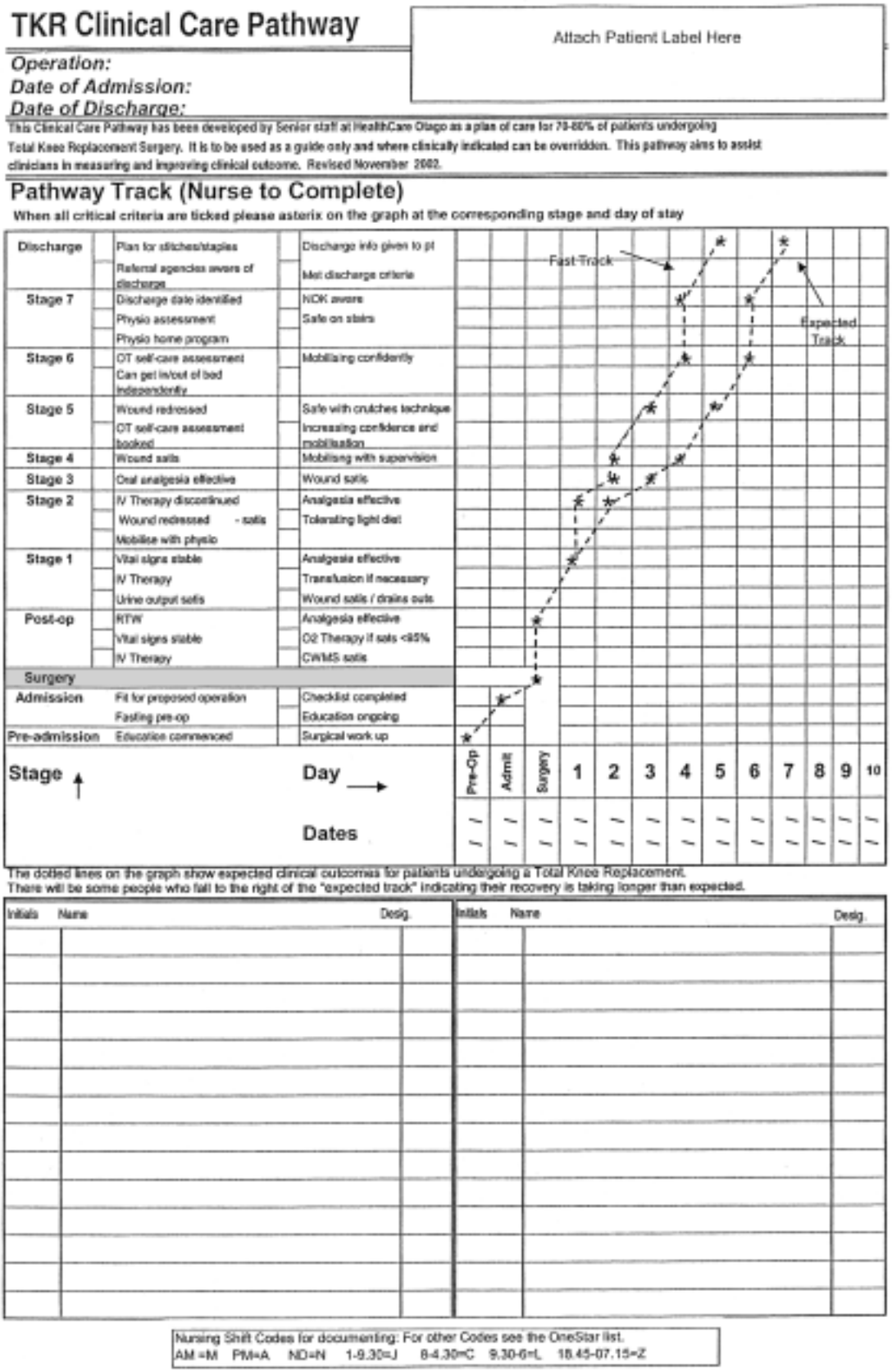
Medical	
M1	Medical assessment completed
M2	Drains removed
M3	No wound ooze
M4	n/v status
M5	Urine output within normal limits
M6	No evidence of DVT
M7	Blood results normal
M8	Chest clear
M9	X-Ray ordered
M10	Analgesia effective - PCA/EPI/Fnblock
M11	Leg position checked
M12	Other: see variance

Nursing				
Observations		M	A	N
N1	Obs within normal limits 4hrly QID (circle)			
Wounds & skin				
N2	Dressing changed signed & dated			
N3	Drains removed			
N4	PAC given			
N5	Pressure Sore Assessment <11 (give no)			
Treatments				
N6	TEDs insitu (if able)			
N7	DVT prophylaxis per guidelines			
N8	Leg exercises completed			
N9	Discontinue if O2 satn > 95%			
N10	Antibiotics stopped cont. oral (circle)			
N11	Coughing & deep breathing ex completed			

Nursing Continued...		M	A	N
N12	CWMS within normal limits			
Nutrition & Hydration				
N13	IV therapy cont. plugged out (circle)			
N14	Tolerating light diet			
Pain control				
N15	Analgesia effective/comfortable at rest			
N16	PCA / Epidural cont removed			
N17	Analgesia bolus given prn			
N18	Seen by Pain Team			
Elimination				
N19	Output satisfactory (IDC out Y / N)			
N20	Bowel function appropriate			
Hygiene				
N21	Full hygiene bedrest cares given			
Psychosocial				
N22	Mood and behaviour appropriate			
Activity & Rest				
N23	Sleeping/Resting adequately			
N24	Front graph completed			
N25	Other : see variance			

Physiotherapy		0800-12.30	1300-1700
P1	Leg mobilised on CPM ..... to ..... deg		
P4	Static quads Y / N SLRaise Y / N IRQ Y / N		
P8	Knee flexion active to 40 deg		
P6	Quads lag is		
P2	Leg in foam trough		
P7	Mob X's /frame bed-chair Scott brace removed		
P10	Other : see variance		

Figure 1 Day 2 total knee replacement clinical care pathway.



TKR Clinical Care Pathway

Attach Patient Label Here

Operation:
Date of Admission:
Date of Discharge:

This Clinical Care Pathway has been developed by Senior staff at HealthCare Otago as a plan of care for 70-80% of patients undergoing Total Knee Replacement Surgery. It is to be used as a guide only and where clinically indicated can be overridden. This pathway aims to assist clinicians in measuring and improving clinical outcome. Revised November 2002.

Pathway Track (Nurse to Complete)

When all critical criteria are ticked please asterix on the graph at the corresponding stage and day of stay

Discharge	Plan for stitches/staples	Discharge info given to pt
	Referral agencies aware of discharge	Met discharge criteria
Stage 7	Discharge date identified	NOK aware
	Physio assessment	Safe on stairs
	Physio home program	
Stage 6	OT self-care assessment	Mobilising confidently
	Can get in/out of bed independently	
Stage 5	Wound redressed	Safe with crutches technique
	OT self-care assessment booked	Increasing confidence and mobilisation
Stage 4	Wound satis	Mobilising with supervision
Stage 3	Oral analgesia effective	Wound satis
Stage 2	IV Therapy discontinued	Analgesia effective
	Wound redressed - satis	Tolerating light diet
	Mobilise with physio	
Stage 1	Vital signs stable	Analgesia effective
	IV Therapy	Transfusion if necessary
	Urine output satis	Wound satis / drains outs
Post-op	RTW	Analgesia effective
	Vital signs stable	O2 Therapy if sats <95%
	IV Therapy	CWMS satis
Surgery		
Admission	Fit for proposed operation	Checklist completed
	Fasting pre-op	Education ongoing
Pre-admission	Education commenced	Surgical work up

Fast-Track

Expected Track

Stage ↑

Day →

Dates

Pre-Op | Admit | Surgery | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10

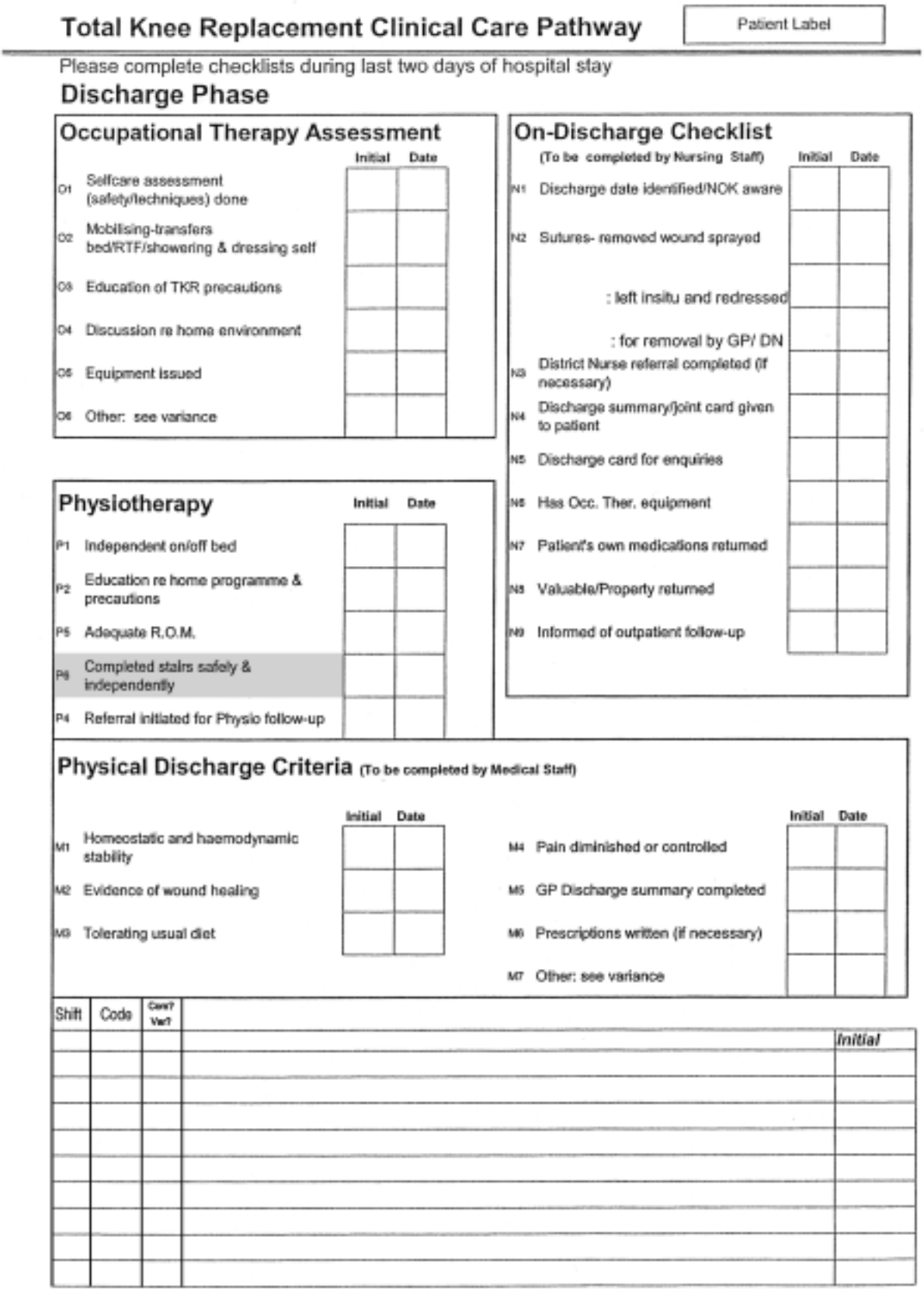
The dotted lines on the graph show expected clinical outcomes for patients undergoing a Total Knee Replacement.
There will be some people who fall to the right of the "expected track" indicating their recovery is taking longer than expected.

Initials	Name	Desig.

Initials	Name	Desig.

Nursing Shift Codes for documenting: For other Codes see the OneStar list.
AM =M PM=A ND=N 1-9.30=J 8-4.30=C 9.30-6=L 18.45-07.15=Z

Figure 2 Progress page of clinical care pathway.



Total Knee Replacement Clinical Care Pathway

Patient Label

Please complete checklists during last two days of hospital stay

Discharge Phase

Occupational Therapy Assessment

		Initial	Date
O1	Selfcare assessment (safety/techniques) done		
O2	Mobilising-transfers bed/RTF/showering & dressing self		
O3	Education of TKR precautions		
O4	Discussion re home environment		
O5	Equipment issued		
O6	Other: see variance		

On-Discharge Checklist

	(To be completed by Nursing Staff)	Initial	Date
N1	Discharge date identified/NOK aware		
N2	Sutures- removed wound sprayed		
	: left insitu and redressed		
	: for removal by GP/ DN		
N3	District Nurse referral completed (if necessary)		
N4	Discharge summary/joint card given to patient		
N5	Discharge card for enquiries		
N6	Has Occ. Ther. equipment		
N7	Patient's own medications returned		
N8	Valuable/Property returned		
N9	Informed of outpatient follow-up		

Physiotherapy

		Initial	Date
P1	Independent on/off bed		
P2	Education re home programme & precautions		
P5	Adequate R.O.M.		
P6	Completed stairs safely & independently		
P4	Referral initiated for Physio follow-up		

Physical Discharge Criteria (To be completed by Medical Staff)

		Initial	Date
M1	Homeostatic and haemodynamic stability		
M2	Evidence of wound healing		
M3	Tolerating usual diet		
M4	Pain diminished or controlled		
M5	GP Discharge summary completed		
M6	Prescriptions written (if necessary)		
M7	Other: see variance		

Shift	Code	Cont? Var?		Initial

Figure 3 Discharge phase of clinical care pathway.

physiotherapy and occupational therapy staff from both in-patient and out-patient / preadmissions areas. The pathway was a protocol that was translated into the backbone of the patient's medical chart. It commenced at the preadmissions clinic with the medical, anaesthetic, and physiotherapy assessment. The nursing assessment included a pressure score and falls risk score. The patient received an overview of both the in-patient and out-patient programmes. Medical, nursing, and physiotherapy tasks or goals were set for each postadmission day (Fig. 1). The medical chart, which was monitored daily, had points that were signed off by the relevant professionals until the day of discharge. Deviations from the expected progress were also recorded. The pathway was initially set for an 8-day postoperative LOS. An overview of progress was recorded on the front of the pathway chart (Fig. 2). Discharge criteria included active knee flexion to 90°, ability to walk with aids on stairs, independent showering, unaided transfers, and dressing, etc. (Fig. 3)

A retrospective and comparative study was performed on all patients undergoing primary TKA over a 5-year period from 1 January 1995 to 31 December 1999 in Dunedin Hospital, Dunedin. During the 30-month period prior to the introduction of the pathway, 181 TKAs were performed. This group of patients (group 1) became the control group in this study. In the consecutive 30-month period following its introduction, there were 261 TKAs performed. This group of patients (group 2) underwent the pathway. In both groups, we only studied cases of elective primary TKAs. Acute, revisional, bilateral, and unicompartmental procedures were excluded from both groups. Procedures were performed by, or under the direct supervision of, 6 consultant orthopaedic surgeons.

All group 2 patients were assessed at the preadmissions clinic for suitability for introduction to the pathway. Patients were not enrolled onto the pathway if they had significant concomitant medical or mobility problems that would affect a standard postoperative stay and recovery. These problems included severe multiple-joint involvement, severe cardiac or respiratory diseases, and potential intensive care or coronary care admissions in the immediate postoperative period. However, the patients excluded from enrolment onto the clinical pathway were included for data analysis in group 2 in order to prevent bias in the study, and to allow comparison with similar patient populations.

One group 1 patient and 2 group 2 patients died postoperatively. The 2 groups were comparable with respect to place of residence, age, sex, underlying diagnosis and co-morbidities (Table 1).

Outcome examined included the LOS, admissions on the day of surgery, complications, readmissions within 90 days, and discharge destination. Patients' daily performance and that at discharge were recorded for group 2 as part of the pathway documentation. During the period of the study, there was no change in the type of implant, operating theatre protocol, or physiotherapy technique used. Guidelines for referral to rehabilitation included poor progression along the pathway, general frailty, problems with activities of daily living, and poor support at home. Data were collected from the hospital's electronic patient administration database, the departmental audit system, the clinical pathway system, and the patient medical records.

Table 1
Demographic and clinical features*

Variable	Group 1 (n=181)	Group 2 (n=261)
Mean age ± standard deviation (years)	69 .8± 8.7	71 .2± 9.4
Sex		
Male	81 (44.8%)	102 (39.1%)
Female	100 (55.2%)	159 (60.9%)
Underlying disease		
Osteoarthritis	170 (93.9%)	232 (88.9%)
Rheumatoid arthritis	11 (6.1%)	29 (11.1%)
Place of residence		
Rural	79 (43.6%)	95 (36.4%)
Town	102 (56.4%)	166 (63.6%)
American Society of Anesthesiologists score category		
I	31 (17.1%)	15 (5.7%)
II	107 (59.1%)	184 (70.5%)
III	43 (23.8%)	61 (23.3%)
IV	0 (0%)	1 (0.4%)

* Data shown in No. (%) except otherwise stated

Statistical analysis

Chi squared and Fisher's exact tests were used to assess the differences between the groups for discrete variables. Student's *t* test was used for continuous variables. Any p value less than 0.05 was considered statistically significant.

RESULTS

Within group 2, 241 (92%) patients were accepted onto the pathway, of whom 209 (87%) patients completed the pathway satisfactorily. LOS was found to be significantly reduced for all patients in group 2 compared with those in group 1. The mean LOS was reduced from 12.9 days in group 1 to 10.3 days in group 2 ($p<0.0001$). The percentage of patients discharged within 8 postoperative days rose from 23.8% in group 1 to 62.8% in group 2 ($p<0.0001$). The rate of admission on the day of surgery increased from 2.2% in group 1 to 4.2% in group 2, but such difference was not statistically significant. There was also an insignificant increase in the rate of utilisation of the in-patient rehabilitation unit from 6.6% in group 1 to 11.9% in group 2. Those patients who required rehabilitation were transferred to the rehabilitation unit. The mean LOS for rehabilitation was 13.4 days in group 1, compared with 10.6 days in group 2 ($p<0.05$). The difference of readmission rate (12.2% for group 1 and 10.3% for group 2) between the 2 groups was not statistically significant either. The results are summarised in Table 2.

The overall rate of complications dropped from 32.6% in group 1 to 25.7% in group 2. In particular, the number of patients requiring manipulation under anaesthesia was reduced in group 2. There were also significantly fewer patients complicated with deep vein thrombosis or pulmonary embolism in group 2. Conversely, there was an insignificant increase in the rate of reported superficial wound infection from 5.5% in group 1 to 9.2% in group 2. There was neither a corresponding difference in the rate of deep wound or joint infection nor a significant increase in the rate of revision procedures between both groups. The results are summarised in Table 3.

Review of the prospectively gathered performance data for the patients in group 2 showed that by postoperative day 8, 89% of these patients attained 90° of knee flexion (93% of whom were further capable of mobilising independently and safely both on the flat and on stairs).

DISCUSSION

A care pathway integrates the routine aspects of a patient's care. Ideally it avoids delay in identifying potential problems and streamlines care accordingly. During the study period we accepted 92% of the patients onto the pathway. With increased experience we now find it extremely rare to exclude a patient from the pathway.

Table 2
Length of stay, admission day, and use of rehabilitation service*

	Group 1 (n=181)	Group 2 (n=261)	p value
Admission on day of surgery	4 (2.2%)	11 (4.2%)	0.296
Mean length of stay±standard deviation (days)	12 .9±4.7	10 .3±3.4	<0.0001
Patients discharged within 8 postoperative days	43 (23.8%)	164 (62.8%)	<0.0001
Patients transferred to rehabilitation unit	12 (6.6%)	31 (11.9%)	0.067
Patients readmitted within 90 days	22 (12.2%)	27 (10.3%)	0.551

* Data shown in No. (%) except otherwise stated

Table 3
Postoperative complications*

	Group 1 (n=181)	Group 2 (n=261)	p value
Patients with one or more complications	59 (32.6%)	67 (25.7%)	0.113
Type of complication			
Manipulation under anaesthetic required	10 (5.5%)	6 (2.3%)	0.074
Deep vein thrombosis/pulmonary embolism	7 (3.9%)	2 (0.8%)	<0.05
Superficial infection	10 (5.5%)	24 (9.2%)	0.154
Deep infection	0 (0%)	1 (0.4%)	1.000
Revision procedure	1 (0.6%)	3 (1.1%)	0.648

* Data shown in No. (%) except otherwise stated

There was a significant reduction in the LOS for patients admitted onto our pathway. Our reduction of 2.6 days was comparable to those of 2 days by Pearson et al.,[7] 1.5 days by Dowsey et al.,[3] and 3.6 days by Fisher et al.[4] Although Mabrey et al.[6] achieved a 6.2 days' reduction, their patient population had a mean age of 10 years less than that of our study. In contrast to Pearson et al.,[7] who admitted 75.6% of their patients on the day of surgery, our admission rate on the day of surgery was very low in both groups (2.2% in group 1, and 4.2% in group 2). Since 39% of our patients were from rural abodes, further measures can be implemented to increase the same-day admission rate, which helps to reduce the LOS.

We propose that different care pathways for TKA should have similar core components such as early discharge planning and in-patient physiotherapy; but we still have to be sensitive to institution-specific requirements. Our pathway emphasises early discharge planning, patient education, and early mobilisation with out-patient physiotherapy. We did not increase staff numbers or add services. Pearson et al.[7] set their LOS at 8 days, transferring patients from the acute ward to a convalescent ward on day 4. They also developed a structured approach to home physiotherapy. Mabrey et al.[6] set a 5-day stay with different discharge criteria, such as 65° active knee flexion and the ability to walk 50 feet with aids (stair climbing was not mentioned). In-patient rehabilitation was required for 20% of those patients and home physiotherapy for a further 17%. Dowsey et al.[3] routinely used community nurses for 3 weeks following discharge.

We found an insignificant increase in the rate of transfer to an in-patient rehabilitation facility in the pathway group. This did not account for the overall reduction in the length of patient stay. We believe that the increased and earlier utilisation of rehabilitation services is largely a result of the clinical pathway. This clinical pathway helps to identify those patients who will benefit from rehabilitation earlier, prompting timely referral.

While there may be concerns about the potential for adverse outcomes with early discharge of patients, our study shows that such concerns are not verified by empirical data. By day 8 of the pathway, 89% of the enrolled patients had over 90° of knee flexion, and 93% of whom were mobilising satisfactorily. These patients thus met the historical criteria for discharge, which were also applied to the patients in group 1. In addition, we found no increase in either postoperative complications or readmissions after the pathway implementation, which is consistent with other studies.[3,6,7] Furthermore, readmissions and most complication types (especially thromboembolic phenomenon) showed a downward trend.

There are inherent weaknesses in this retrospective study. It is difficult to confidently conclude that the improvements were mainly attributed to the introduction of the pathway. However, since the selected patients were from the same institution and were well matched with respect to age, American Society of Anesthesiologists score, sex, and diagnosis, it is highly probable that the use of a pathway was a major factor influencing the changes. Our tentative conclusion is also supported by the fact that there were no major changes in indications, staff, surgical technique or implants during the study period.

The pathway is also a useful audit tool. By analysing the variations recorded, we were able to identify potential complications such as wound oozing caused by the administration of low-molecular-weight heparin, and urinary retention following spinal anaesthesia. This early awareness can help us modify our practice accordingly.

CONCLUSION

This study adds to the growing evidence that the use of a clinical pathway can be an aid to streamline the care of patients with a consequent reduction in the LOS without detrimental effect.

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CE

1.5 ANCC Contact Hours

Enhanced Recovery After Surgery for Hip and Knee Replacements

David P. Gwynne-Jones ▼ Ginny Martin ▼ Chris Crane

BACKGROUND: Enhanced recovery after surgery (ERAS) programs or hip and knee replacements have had a significant effect on streamlining patient care with shorter stays, no increase in complications, and improved outcomes including reduced mortality.

PURPOSE: To compare outcomes following the introduction of an ERAS program for hip and knee replacements developed at our institution with a historical cohort of patients.

METHODS: ERAS protocols were developed at our institution for patients undergoing hip and knee joint replacements. Key aspects were changes in preadmission, a new education session, improved management of perioperative anemia, standardized anesthetic guidelines, day of surgery mobilization, and improved discharge planning. The results of the first 18 months (528 consecutive patients) were compared with those of a historical cohort of 507 patients from the 18 months prior to their introduction.

RESULTS: In the ERAS group, the mean age was 68.3 years for patients who underwent hip replacement and 70.4 years for patients who underwent knee replacement. Thirty-two percent of patients were ASA (American Society of Anesthesiologists) Grades III and IV. The average preoperative Oxford score was 11. The average length of stay (ALOS) fell from 5.6 to 4.3 days for patients who underwent hip replacement and from 5.7 to 4.8 days for patients who underwent knee replacement ($p < .001$). Ninety-six percent of patients were discharged home. The 30-day readmission rate increased from 3.2% to 5.5% ($p = .065$). Six-month Oxford knee scores were higher in the ERAS group (39.8 vs. 36.3, $p = .03$). There was no increase in mortality or early revision rate.

CONCLUSIONS: Substantial reductions in ALOS can be gained with the introduction of ERAS protocols, with high patient satisfaction and no increase in complications in a consecutive unselected group of public hospital patients. This requires a multidisciplinary approach and a strong clinical input.

Background

Enhanced recovery after surgery (ERAS) programs, also known as enhanced recovery programs (ERPs), fast track, or rapid recovery, are based on the work of Henrik Kehlet in colorectal surgery (Kehlet, 1997). In recent years, there has been considerable interest in their introduction in orthopaedic surgery, especially in hip and knee replacements (Ibrahim, Twaij, Giebaly, Nizam, & Haddad, 2013; Kehlet & Thienpont, 2013). Programs are designed to prepare patients for, and reduce the total impact of, surgery, helping them recover more quickly. These programs include preoperative information and optimization of comorbidities, anesthetic and postoperative analgesia, surgical technique, perioperative blood management, early mobilization, rehabilitation, and discharge planning (Kehlet & Thienpoint, 2013). Such programs take a whole-system, evidence-based, multidisciplinary approach (Ibrahim et al., 2013; Kehlet & Thienpoint, 2013). In orthopaedics, they may reduce mortality, average length of stay (ALOS), and perioperative complications without an increase in complication or readmission rates (Kearney, Jennrich, Lyons, Robinson, & Berger, 2011; Malviya et al., 2011; McDonald, Siegmeth, Deakin, Kinninmonth, & Scott, 2012; Wainwright & Middleton, 2010). As there are approximately six times more elective hip and knee replacements performed per year in the United Kingdom than colorectal procedures, the potential benefits may be greater (Wainwright & Middleton, 2010).

Despite the success of ERAS programs, there have been few published results in Australasia (Keane et al., 2012). We developed and implemented ERAS protocols as part of a wider program—the Orthopaedic Patient Pathway funded by the Ministry of Health, under the Elective Services Productivity and Workforce Program. The purpose of this article is to describe the development, implementation, and results of the first 18 months of the program in our public hospital. The first 528 patients undergoing primary hip or knee replacement following the introduction of the ERAS program were

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compared with a historical cohort from the 18-month period immediately prior to their introduction.

Methods

Our institution is the main hospital for a population of 200,000, covering a sparsely populated area of 32,000 square kilometers. There are 10 orthopaedic surgeons and one arthroplasty fellow who perform approximately 400 hip and knee arthroplasties including revision surgery per year. Elective patients are admitted to a single orthopaedic elective ward (20–24 beds). In addition to the normal ward nursing staff, there is one permanent orthopaedic physiotherapist, a rotating physiotherapist, and one occupational therapist. Key members of the department (including the elective ward charge nurse, the senior permanent physiotherapist, and the clinical leader) attended a 1-day workshop on the principles and implementation of enhanced recovery (Wainwright & Middleton, 2010). Having been enthused by the presentation, the team members resolved to introduce the techniques to our institution. Over the next 6 months, all aspects of the patient journey were reviewed. Small-scale audits were conducted on cancellations at the preadmission clinic and on day of surgery, effect of preoperative anemia on transfusion requirements and ALOS, use of drains, use of femoral nerve blocks, and local anesthetic infiltration techniques. New protocols were developed by the nursing, physiotherapy, and medical staff. An experienced former orthopaedic charge nurse was appointed to a part-time ERAS facilitator role, and the head orthopaedic surgeon was the *clinical champion* for the project.

An audit of cancellations at the preadmission clinic showed the commonest reasons for cancellation of surgery were poorly controlled medical conditions, need for dental care, and skin problems such as ulcers. This led to the development of a preoperative health questionnaire concentrating specifically on recent dental care, skin lesions, and chronic health conditions. This was mailed to patients and general practitioners (GPs) prior to the preadmission appointment. Problems were identified and addressed, and surgery was delayed if necessary. An audit of preoperative anemia showed that patients who were anemic (males <130 g/L, females <120 g/L) stayed a mean 1.6 days longer than those patients who were not anemic (6.8 vs. 5.2 days) and 56% of anemic patients required transfusion compared with 12.5% of nonanemic patients. This led to the development, in conjunction with the Hematology Department, of an algorithm for the early identification and management of preoperative anemia. Facilities and arrangements for intravenous iron infusion and oral iron supplementation were developed for patients with preoperative iron-deficient anemia.

Community service physiotherapists and occupational therapists had seen patients from the historical cohort for education and aids such as raised toilet seats and crutches. Although education was given, this was not always consistent or up to date. A new preoperative education class was developed for all patients who lived within 1-hour travel time from our hospital and run by members of the elective ward staff. Aids were issued, and patients were instructed on preoperative physiotherapy exercises. Details of their postoperative care and expectations were given by the staff who would be looking after them, which ensured continuity. The patient information guide was rewritten to reflect a shifting of responsibility onto the patient and the family in areas such as smoking cessation and discharge planning.

Standardized anesthetic and analgesia guidelines were developed with a consultant anesthetist (see Table 1). The goal was for mobilization of the patient on the day of surgery if possible and better management of postoperative pain. Key initiatives included the routine administration of tranexamic acid (if no contraindications) and increased use of parenteral and oral nonsteroidal anti-inflammatory drugs. A randomized study we conducted showed no advantages to postoperative continuous femoral nerve infusions over a single-shot femoral nerve block, so their use was discouraged (Wyatt, Wright, Locker, Stout, & Theis, 2015). In turn, femoral nerve block has been superseded by local infiltration with ropivacaine, adrenaline, and tranexamic acid in patients undergoing knee replacements.

Discharge criteria were developed so that in a medically fit patient the final decision on discharge is made by the nursing and physiotherapy staff. Patients should be independent for transfers in and out of bed, have managed stairs and showering, and have satisfactory knee flexion (for knee replacement patients) prior to discharge. The ERAS team consulted and discussed the new protocols with all orthopaedic surgeons, junior doctors, anesthetists, nursing staff, inpatient and outpatient physiotherapists, and local GPs.

Following discussion and small-scale trials, the new protocols were implemented in January 2013. Key aspects are summarized in Table 2.

This study compares a consecutive series of all patients undergoing primary elective total hip (THR) or knee replacement (TKR) from January 1, 2013, to June 30, 2014, with a historical control cohort from the preceding 18-month period, July 1, 2011, to December 31, 2012. Revision surgery and hip replacement for acute fractures were excluded. Data including age, gender, body mass index (BMI), ALOS, time of discharge, transfusion requirements, and acute readmissions were collected prospectively.

Baseline data collected included the American Society of Anesthesiologists (ASA) grade. This has five grades, where ASA I is a healthy patient, ASA II is a patient with mild systemic disease, ASA III is a patient with severe systemic disease, and ASA IV is a patient with severe systemic disease that is a constant threat to life. ASA V is a moribund patient who is not expected to survive without the operation and is not relevant to elective joint replacement. (ASA, 2014) Preoperative Oxford hip or knee scores (OHS, OKS), which are used in our prioritization process, were also collected for the ERAS group. The Oxford score is a 12-question patient-reported outcome measure. There are five questions on pain and seven on function, each of which has five options and is scored 0–4, where 0 is worst and 4 is best. This gives a score of 0–48, where 48 is best. The score is validated and widely used to report the improvement

Table 1. Anesthesia Guideline for THJR/TKJR

This is only a guideline. It is recognized that the attending anesthetist may find it necessary to alter this in certain circumstances depending on the patient's individual needs. Please contact APS early if the patient is opioid tolerant.
Spinal anesthesia +**intrathecal morphine** 100–150 μg
Sedation or **light general anesthesia**
Maintain spontaneous ventilation where possible
Maintain **normothermia**
Cefazolin 2 g prior to skin incision and tourniquet inflation
Consider **tranexamic acid** 15 mg–20 mg/kg iv slowly prior to incision if excessive blood loss is expected or the patient is anemic (Hb <130 g/L, males, 120 g/L females)
Avoid excessive **fluids**, i.e., 1–2 L in routine cases; aim for approximately 3 L in the first 24 hours
Paracetamol 2 g as a premed or 1 g iv intraoperatively
Parecoxib 40 mg iv if not contraindicated, i.e., allergy, severe asthma, PUD, abnormal creatinine, >75-year-old. Consider continuing for 3 days postop
TKJR only
Femoral nerve block (single shot): Bupivacaine 100 mg, or ropivacaine 150 mg + dexamethasone 8 mg
OR **Peri/intra-articular local anesthetic:** Ropivacaine 200–300 mg + adrenaline 1 mg + 1 g tranexamic acid (in place of IV dose made up to 100 mL with normal saline)
Postoperative analgesia to consider
Paracetamol 1 g qid regular
Ibuprofen 200–400 mg 8 hourly 3 days and then stop + omeprazole 40 mg od while on Ibuprofen
PCA for 1–2 days for patients who underwent knee replacement started in recovery; prn for patients who underwent hip replacement
Oxycontin Knees only 10 mg bd. Start postop Day 1 for 3 days and then stop
Oxynorm 5–10 mg po q3h prn (not while on PCA) review on D/C
Clonidine patch tts1 start once mobilizing (Day 1)
Tramadol 50–100 mg qid/prn (avoid if SSRIs, previous intolerance, seizures)

Note. bd = twice daily; D/C = discharge; od = once daily; Hb = hemoglobin; iv = intravenous; PCA = patient-controlled analgesia; po = per os or orally; prn = as needed; PUD = peptic ulcer disease; qid = four times a day; q3h = every 3 hours; SSRI = serotonin-specific reuptake inhibitor; THJR = total hip joint replacement; TKJR = total knee joint replacement.

and outcome following hip or knee replacement surgery (Murray et al., 2007).

Complications and readmission data were collected from our institution's patient management system, the department's surgical audit system, and the surgical site infection (SSI) surveillance program for hip and knee replacements. Data were cross-referenced with the New Zealand (NZ) Joint Registry for revisions, deaths, and 6-month postoperative Oxford scores. The NZ Joint Registry (2014) collects details of all patients undergoing hip or knee replacement in the country and has 98% compliance.

Table 2. Key Components of the ERAS Program

Early identification and treatment of preoperative anemia
Preoperative health questionnaires to patients and GPs
Weekly preoperative education class run by the ward nursing and allied health staff
Rewritten patient information guide
Streamlined preadmission process
Day of surgery admission for all patients
Standardized anesthetic and analgesia guidelines
Intraoperative local anesthetic infiltration
Perioperative blood management algorithm
Day of surgery mobilization
Development of nurse- and physiotherapy-led discharge criteria

Note. ERAS = enhanced recovery after surgery; GP = general practitioner.

The study was approved by the University of Otago Human Ethics committee (Health). Statistical analysis was performed using Stata v13 (College station, TX). Two-tailed *t* tests were used for continuous variables and chi-square tests for categorical data.

Results

There were 507 patients who underwent primary elective hip and knee replacements in the historical control group and 528 in the ERAS group. The groups were well matched with respect to age, gender, and ASA grade (see Table 3). The mean age for patients who underwent hip replacement was 68 years and for patients who underwent knee replacement was 70 years. In both groups, 30% of patients were ASA Grades III and IV, indicating the presence of severe systemic comorbidities. In the ERAS group, the median BMI was 31.7 kg/m^2 and the mean preoperative OHS was 11.1 (*SD* = 4.9) and OKS was 11.1 (*SD* = 4.0). These data were not available for the historical cohort but are likely to be very similar.

The day of surgery admission rate increased from 96% in the control group to 99% in the ERAS group. The average ALOS for elective THR fell significantly by 1.3 days and by 0.9 days for TKR, with the main drop occurring almost immediately following the introduction of the new protocols, especially for THR (see Figure 1). There was a shift to discharges later in the day during the course of the study. If patients were able to be discharged in the afternoon or evening after their physiotherapy, they did not have to wait for a medical ward round the following day. Patients who were mobilized on the day of surgery had an ALOS 1 day shorter than those who did not. Twenty-one patients (4%) were discharged to a rehabilitation ward or rural hospital bed. The mean age of these patients was 76 years, and 17 (81%) were patients who underwent hip replacement.

Following the introduction of the perioperative anemia management pathway, the transfusion rate dropped from 26% to 17% for patients who underwent hip replacement (p = .18) and was unchanged for patients who underwent knee replacement at 9%. There was a 40% reduction in the number of units of blood transfused per patient. The median length of stay (LOS) for patients with preoperative anemia was 5 days compared with 4 days for nonanemic patients.

Two in-hospital deaths occurred in ASA Grade III patients. A 78-year-old died of aspiration pneumonia after prolonged hypotension following a hip replacement. An 80-year-old developed cardiogenic shock following knee

Table 3. Comparison of Demographic Details and Outcomes of the Two Groups Pre- and Postimplementation of ERAS Changes

	2011–2012 Pre-ERAS	2013–2014 Post-ERAS	*p*
Hip	314	318	
Male:Female	146 (46%):168 (54%)	146 (46%):172 (54%)	.88
Age (years), mean (*SD*)	66.8 (11.8)	68.3 (11.8)	.10
ASA Grades III and IV	93 (30%)	104 (33%)	.40
Mean LOS (*SD*)	5.6 (2.1)	4.3 (1.9)	**<.00001**
Median (IQR)	5 (4–6)	4 (3–5)	
Mean preop Oxford score (*SD*)	Not available	11.1 (4.9)	
Mean 6-month Oxford score (*SD*)	36.6 (8.7)	38.8 (7.8)	.152
Revisions	3 (0.96%)	4 (1.26%)	.7
Knee	193	210	
Male:Female	83 (43%):110 (57%)	107 (51%):103 (49%)	.11
Age (years), mean (*SD*)	69.8 (9.0)	70.4 (8.9)	.54
ASA Grades III and IV	58 (30%)	67 (32%)	.52
Mean LOS (*SD*)	5.7 (1.8)	4.8 (1.8)	**<.00001**
Median (IQR)	5 (5–6)	4 (4–5)	
Mean preop Oxford score	Not available	11.1 (4.0)	
Mean 6-month Oxford score (*SD*)	36.3 (7.4)	39.8 (6.6)	**.03**
Revisions	2 (1.04%)	0 (0%)	.139
Hips and knee combined	507	528	
Deaths 30 days	1 (0.2%)	3 (0.57%)	.336
Deaths 90 days	2 (0.4%)	4 (0.76%)	.442
Readmissions <30 days	16 (3.2%)	29 (5.5%)	.065

Note. ASA = American Society of Anesthesiologists; ERAS = enhanced recovery after surgery; IQR = interquartile range; LOS = length of stay; OHS = Oxford hip score (0–48); OKS = Oxford knee score (0–48). The chi-square test used for categorical data; the *t* test for continuous variables. Boldface indicates statistical significance.

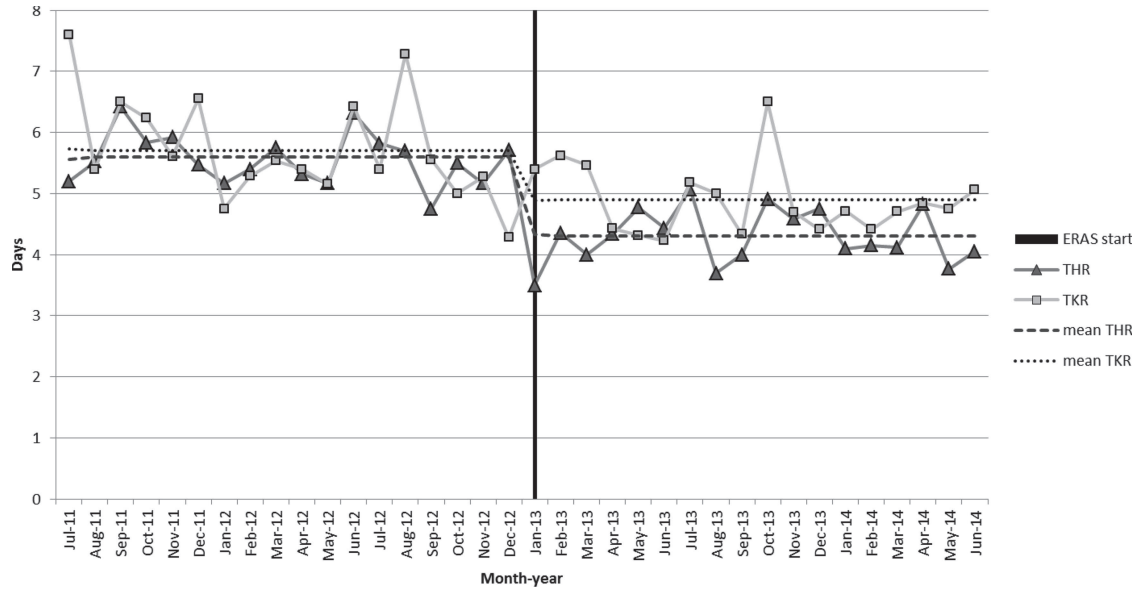

FIGURE 1. Graph showing length of stay by month for primary elective THR and TKR before and after implementation of the ERAS program. ERAS = enhanced recovery after surgery; THR = total hip replacement; TKR = total knee replacement.

replacement and died despite acute coronary artery bypass grafting. Two patients (aged 86 and 79 years, ASA Grade IV with multiple comorbidities) died following discharge to residential care at 30 and 50 days, respectively. The 30-day and 90-day death rates were not significantly different from those of the historical cohort (see Table 3).

There were five confirmed SSIs out of 528 hip and knee replacements (0.9%). Four patients (0.75%) required a return to the operating theater: two patients who underwent knee replacement for superficial infection and wound breakdown, and one patient for a hematoma following hip replacement. A 78-year-old man required revision of an uncemented hip at 4 days due to an early dislocation because of loose undersized components. Three other patients who underwent hip replacement had revision at 28, 133, and 455 days for dislocation, giving a hip revision rate of 1.3%. No patients who underwent knee replacement had revision. The revision rates were not significantly different from those seen in the historical cohort.

There was an increase in the 30-day readmission rate from 3.2% (16 of 507) to 5.5% (29 of 528) (ns, $p = .065$). In the ERAS group, the commonest reasons for readmission were for wound problems and suspected infection ($n = 9$), pain issues ($n = 7$), and concerns regarding leg swelling and deep vein thrombosis ($n = 4$). Only four patients from the historical group were readmitted for these reasons.

Regular qualitative patient surveys were performed, with high satisfaction reported. The 6-month Oxford scores were higher in the ERAS group by 3.5 points for patients who underwent knee replacement ($p = .03$) and 2.2 points for patients who underwent hip replacement (ns, $p = .152$) (see Table 2).

Compared with the historical group, there was a saving of 601 bed nights over the 18-month study period or 400 bed nights per year. This represents a theoretical bed night reduction of 20%. However, in practice, this opened up the beds for additional patients with an increase in elective admissions of 10.7% and 6% for acute admissions, resulting in no significant change in the total number of orthopaedic bed nights. The increase in readmissions led to an extra 97 nights (163 nights vs. 68 nights in the control cohort).

Discussion

There has been a trend toward shorter LOS following hip and knee replacements over the last two decades. Day of surgery admission has become the norm in our unit, and only in exceptional circumstances are patients not admitted on the day of surgery regardless of their place of residence, age, or family supports.

Enhanced recovery initiatives have been shown across the world to improve patient outcomes and can reduce the LOS to 2–4 days for patients undergoing hip and knee replacements even in unselected cohort studies (Kehlet, 2013). In practice, many hospitals have longer stays than this and may discharge patients to rehabilitation facilities rather than home. However, in the United Kingdom, it appears that hospital stays of around 5 days are achievable with the widespread implementation of ERPs in public hospitals and not just in dedicated specialist units (Kehlet, 2013).

This study reports on a consecutive unselected group of the first 528 primary hip and knee replacements performed in our public hospital following the implementation of the ERAS program. No patients were excluded. The mean age of 68 years for patients undergoing hip replacement and 70 years for patients undergoing knee replacement was typical for public hospital patients (Dakin, Gray, Fitzpatrick, MacLennan, & Murray, 2012; Jenkins et al., 2013; Malviya et al., 2011; McDonald et al., 2012; Wainwright & Middleton, 2010). The BMI (31.7 kg/m^2) was higher than NZ averages for hip (28.7 kg/m^2) and knee (31.1 kg/m^2) (NZ Joint Registry, 2015). The proportion of patients with ASA Grades III and IV (32.7%) was higher than that reported by Wainwright

and Middleton (2010; 8.5%) and the NZ Joint Registry (2015; 23%–25%). In our district, we have a population that is older than the national average and has had problems with access to hip and knee replacements (Gwynne Jones, 2013; Gwynne Jones & Iosua, 2016). Many patients undergoing surgery had been waiting for 12–18 months due to financial constraints. Most patients had severe disease and were significantly deconditioned. This is reflected in the average preoperative Oxford score of 11 points for both hip and knee replacements compared with average preoperative Oxford scores of 18–20 points reported by others (Dakin et al., 2012; Jenkins et al., 2013; McDonald et al., 2012). Despite this, we were able to show significant changes in our LOS, with only a small increase in readmission rates. Our median LOS dropped from 5 to 4 days for patients who underwent knee or hip replacements, and the reduction in mean LOS is comparable with other published results from the United Kingdom (Kotze, Carter, & Scally, 2012; Malviya et al., 2011; McDonald et al., 2012; Robinson, Wagstaff, Sanghera, & Kerry, 2014; Wainwright & Middleton, 2010). Units in the United States have reported decreases in LOS of 3.4–3.5 days with similar strategies including preoperative education classes and pain management (Kearney et al., 2011; Parisien, Valentine, Hoffman, & Penzero, 2012). However, LOS figures can be misleading if some patients are discharged to step-down facilities. Large studies from the United States have shown that, despite a mean LOS of 3.9–4.2 days, 34%–48% of patients are discharged to rehabilitation or skilled nursing facilities (Schairer, Vail, & Bozic, 2014; Zmistowski et al., 2013). Our figure of 96% discharged home is very similar to that of the Bournemouth group in England (Wainwright & Middleton, 2010).

It has been shown previously that transfusion is associated with longer hospital stays and readmission rates (Ibrahim et al., 2013; Kotze et al., 2012) and preoperative hemoglobin level predicts ALOS independent of transfusion (Kotze et al., 2012). In our initial audit, we noted that preoperative anemia was associated with an increase in median LOS of 1.5 days. The increase in median LOS is now 1 day. Our transfusion rate remains higher than that of other studies (Irwin et al., 2013; Kotze et al., 2012; Malviya et al., 2011; McDonald et al., 2012). If this can be further reduced, there are potential benefits both in terms of LOS and in the costs of blood transfusion.

The complication rate has not increased significantly. Our SSI rate of 0.9% is similar to the NZ average of 1.2% (Morris, 2014) and at this stage no deep infections have been identified. The return-to-theater rate of 0.75% compares favorably with reported rates of 1.3%–1.8% (Irwin et al., 2013; Malviya et al., 2011). The 30-day readmission rate increased from 3.2% to 5.5%, but this is still similar to the 28-day readmission rates of 3.1%–8.5% reported by others (Irwin et al., 2013; Malviya et al., 2011; Schairer et al., 2014; Wainwright & Middleton, 2010; Zmistowski et al., 2013). It is concerning that the number of readmissions directly related to the orthopaedic procedure such as wound problems, pain, and swelling has increased. It is not clear whether this is related to the age and comorbidities of the patients or early discharge.

The 30-day and 90-day death rates of 0.57% and 0.76% are a little higher than those reported in other contemporary series (Cusick & Beverland, 2009; Hunt et al., 2013; Malviya et al., 2011; Sharrock, Della Valle, Go, Lyman, & Salvati, 2008). This may reflect the high proportion of patients who were ASA Grades III and IV. Malviya et al. (2011) reported a reduction in mortality rates, with ERPs from 0.5% to 0.1% in an unselected group of patients of a similar age, but did not report ASA grade. Data from the U.K. registry have shown a reduction in 90-day mortality from 0.56% to 0.29% over the 8 years from 2003 to 2011 (Hunt et al., 2013).

Like others, we found patient satisfaction was high (Jones et al., 2014; Kearney et al., 2011; Parisien et al., 2012). The education classes were particularly well received. The 6-month postoperative OKSs of 39.8 in the ERAS group were 3.5 points higher than those of the historical group and higher than the NZ average of 37.4 (NZ Joint Registry, 2015). The minimum clinically important difference in Oxford score has been reported as 5 points but may be as little as 2 points (Beard et al., 2013; Murray et al., 2007). Therefore, patients in the ERAS had at least equivalent outcomes at 6 months to the historical cohort. The early revision rate (1.3% at minimum 18-month follow-up) for patients who underwent hip replacement is comparable with the NZ Joint Registry rate of 1.1% at 1 year and 1.6% at 2 years (NZ Joint Registry, 2015).

A strength of this study is that it reports on a consecutive group of patients presenting to a general public hospital with significant comorbidities and severe symptoms. There were multiple surgeons and anesthetists of varying grade involved in the surgery, and a variety of implants were used. This suggests that the interventions are generalizable and similar results can be achieved in other institutions.

A limitation of our study is the use of a historical control group, although the patients were well matched. During the development of our protocols, we noted a small drop in ALOS. In the first 6 months of the historical cohort period, the ALOS was 5.8 days for patients who underwent hip replacement and 6.1 days for patients who underwent knee replacement. The ALOS had fallen to 5.4 days for patients who underwent hip replacement and 5.5 days for patients who underwent knee replacement by the date we formally *went live*. The dramatic drop after this date is particularly evident for patients who underwent hip replacement and strongly suggests that the gains were due to the new program. If we took the first 6-month period of the control group as our baseline, then the potential benefits would increase to 500 bed nights per year. This is in part offset by the increased bed nights due to readmissions.

Some of the improvements were small and may not, on their own, have been shown to have a statistically significant effect. However, a key component of programs such as these is the *aggregation of marginal gains* (Durrand, Batterham, & Danjoux, 2014). The end result of all the small changes has resulted in significant reductions in key outcomes such as LOS.

For a project such as this to succeed, strong clinical input is needed. It proved critical to engage and enthuse the senior nursing and allied health staff on the ward.

Most of the changes instituted were nurse or physiotherapist led. The change in attitudes of surgeons and the junior medical staff followed. Many of the changes can be implemented without any increase in budget. A key failing of the project was that there were no mechanisms to return any of the gains to the department for the benefit of orthopaedic patients. Sustainability has been a challenge. Increasing financial pressures, the loss of key staff, medical outliers on the orthopaedic ward, and nursing shortages are constant threats to the continuing success of the program.

Conclusion

Enhanced recovery programs for patients undergoing hip and knee replacements can significantly reduce the LOS without relying on step-down or rehabilitation facilities. They are effective for an unselected public hospital population with severe osteoarthritis and significant comorbidities and have good outcomes, high patient satisfaction, and no increase in complications. Strong nursing, physiotherapy, and clinical leadership and a multidisciplinary approach are required.

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Original Article

Cardiopulmonary exercise testing in severe osteoarthritis: a crossover comparison of four exercise modalities*

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Summary

Cardiopulmonary exercise testing is performed increasingly for cardiorespiratory fitness assessment and pre-operative risk stratification. Lower limb osteoarthritis is a common comorbidity in surgical patients, meaning traditional cycle ergometry-based cardiopulmonary exercise testing is difficult. The purpose of this study was to compare cardiopulmonary exercise testing variables and subjective responses in four different exercise modalities. In this crossover study, 15 patients with osteoarthritis scheduled for total hip or knee arthroplasty (mean (SD) age 68 (7) years; body mass index 31.4 (4.1) $kg.m^{-2}$) completed cardiopulmonary exercise testing on a treadmill, elliptical cross-trainer, cycle and arm ergometer. Mean (SD) peak oxygen consumption was 20-30% greater on the lower limb modalities (treadmill 21.5 (4.6) ($p < 0.001$); elliptical cross-trainer (21.2 (4.1) ($p < 0.001$); and cycle ergometer (19.4 (4.2) $ml.min^{-1}.kg^{-1}$ ($p = 0.001$), respectively) than on the arm ergometer (15.7 (3.7) $ml.min^{-1}.kg^{-1}$). Anaerobic threshold was 25-50% greater on the lower limb modalities (treadmill 13.5 (3.1) ($p < 0.001$); elliptical cross-trainer 14.6 (3.0) ($p < 0.001$); and cycle ergometer 10.7 (2.9) ($p = 0.003$)) compared with the arm ergometer (8.4 (1.7) $ml.min^{-1}.kg^{-1}$). The median (95%CI) difference between pre-exercise and peak-exercise pain scores was greater for tests on the treadmill (2.0 (0.0-5.0) ($p = 0.001$); elliptical cross-trainer (3.0 (2.0-4.0) ($p = 0.001$); and cycle ergometer (3.0 (1.0-5.0) ($p = 0.001$)), compared with the arm ergometer (0.0 (0.0-1.0) ($p = 0.406$)). Despite greater peak exercise pain, cardiopulmonary exercise testing modalities utilising the lower limbs affected by osteoarthritis elicited higher peak oxygen consumption and anaerobic threshold values compared with arm ergometry.

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Cardiopulmonary exercise testing (CPET) is considered the gold standard tool for evaluating cardiorespiratory fitness [1], and exercise capacity is a well-established predictor of cardiovascular and all-cause mortality [2]. Low peak oxygen consumption ($\dot{V}O_2$) and/or anaerobic threshold values can make performing activities of daily living difficult and in the

surgical setting are associated with an increased risk of adverse outcomes following a range of surgical procedures [3, 4]. Cardiopulmonary exercise testing is used as an objective pre-operative risk assessment tool by identifying patients who may be more vulnerable to the stress of surgery and thereby may benefit from more intensive peri-operative care [1, 3].

Patients presenting for major surgical procedures, where CPET is particularly prognostically useful, often have other comorbidities, some of which can limit their ability to perform traditional cycle CPET. Lower limb osteoarthritis is a condition prevalent in older adults that can significantly impair lower limb exercise; only 60% of participants with lower limb osteoarthritis were able to use a cycle ergometer for exercise testing in a feasibility study [5]. Because of lower limb impediments, arm ergometry is often used as a substitute; however, peak $\dot{V}O_2$ values are approximately 30% lower than those obtained during cycle ergometry in healthy individuals and those with coronary and peripheral artery disease [6–9]. Comparative arm ergometry data do not exist in the literature in patients with hip and knee osteoarthritis, although it is feasible that arm ergometry in this cohort could enable achievement of higher CPET values by utilising the unaffected upper limbs. Furthermore, the elliptical cross-trainer has been shown to evoke similar peak $\dot{V}O_2$ values to treadmill testing in healthy individuals [10]. It is unknown how suitable this modality is for CPET in any clinical cohort, particularly patients with osteoarthritis. Lastly, the treadmill is an exercise modality readily available in hospital settings, preferred by cardiologists due to its ability to achieve higher work-loads (and thus higher cardiorespiratory response), compared with cycle ergometry [11]; its practicality in an osteoarthritis cohort is unknown. Therefore, these alternative modalities warrant testing in this population.

The prevalence of osteoarthritis is predicted to increase due to an ageing population and increased prevalence of obesity [12]; these population factors are also likely to result in more complex or high-risk surgical procedures. Risk stratification via CPET will become more common and may be critical in operative decision-making. It is therefore essential to know the optimal exercise modality for performing CPET in patients with lower limb osteoarthritis, particularly if traditionally used cycle ergometry is not representative or practical. The primary aim of this study was to compare peak $\dot{V}O_2$ values derived from CPET using treadmill, ellipitical cross-trainer, cycle, and arm ergometer modalities in patients scheduled for total hip or knee arthroplasty. Secondary aims were to compare other CPET-derived and physiological variables and subjective responses across the four CPET modalities.

Methods

This study was a crossover design. Ethical approval for the study was obtained and the trial was registered. Informed consent was obtained and all procedures conformed to the standards set by the Declaration of Helsinki.

Patients with end-stage hip or knee osteoarthritis who were scheduled for hip or knee arthroplasty at a regional public hospital were eligible for inclusion. Patients with any contraindication to non-physician supervised maximal exercise testing were not studied. Contraindications included: moderate to severe aortic and/or mitral stenosis; hypertrophic cardiomyopathy; history of malignant or exertional arrythmias and/or syncope; intracardiac shunt; genetic channelopathies; New York Heart Association class-3 heart failure; severe left ventricular dysfunction and/or severe pulmonary arterial hypertension [13, 14]; cardiovascular event within 3 months (e.g. angina, myocardial infarction); implantable cardioverter defibrillator and/or pacemaker; pathology limiting upper-limb exercise (e.g. shoulder joint osteoarthritis); and any other medical condition deemed a significant risk to study participation.

The primary outcome measure was peak $\dot{V}O_2$. This was assessed by CPET utilising incremental step protocols that had been used previously in patients with severe osteoarthritis; it was not possible to perform ramp protocols using the treadmill or cross-trainer, thus step protocols were employed for all modalities. Expired gas analysis was performed using an online gas analysis system (Quark CPET; COSMED, Rome, Italy). Before each test, calibration of gas and flow was conducted according to manufacturer and published guidelines [1]. Height and body mass were recorded before each test. All participants completed their initial CPET on a stationary, electromagnetically braked cycle ergometer (COSMED E200; COSMED); this ensured a clean and reliable ECG trace could be obtained, which was screened retrospectively by an experienced cardiologist for undiagnosed cardiovascular disease. Immediately following a 5-min warm-up, intensity was increased in steps of 10–20 watts (at the researcher's discretion) every minute until test termination, aiming for an exercise duration of 8–12 min [15]. Participants were asked to maintain a cadence between 60 and 80 rev.min^{-1}.

Following the cycle CPET, the order of exercise modality was allocated at random using a 3x3 Latin square design for the remaining three tests. Treadmill testing was performed using a motorised treadmill (Activate Series Treadmill (OST); Life Fitness, Rosemont, IL, USA). A comfortable but brisk walking speed was determined during the 5-min warm up and this speed was maintained for the duration of the test. Treadmill inclination was

increased every minute by 1%. A commercially available ergometer (Activate Series Cross-Trainer (OSX); Life Fitness) was used for cross-trainer testing. Immediately following a 5-min warm-up, the intensity increased by 10-25 watts every minute [10]. Arm ergometry was performed seated on an electromagnetically-braked ergometer (COSMED E400, COSMED). Participants completed a 3-min warm-up of arm pedalling at 10 watts, after which exercise intensity increased by 10 watts every 2 min; the warm-up was shorter and intensity increased every 2 min as upper-limb exercise uses smaller and less oxidative musculature and the extra warm-up duration and/or more frequent increments may cause premature volitional fatigue [16]. Participants were requested to maintain a crank rate of between 70 and 80 rev.min^{-1} [17].

Expired gases and 12-lead ECG were monitored continuously throughout all testing. Heart rate, blood pressure and subjective measures were recorded during exercise at regular intervals and at test termination [14]. The test was terminated when the participant asked to stop, was unable to maintain the required cadence or at the discretion of the supervising researcher if any termination criteria were present [13]. Following test termination, exercise intensity was lowered to facilitate a very light active recovery.

For each exercise modality, a visual analogue scale (VAS) was used to measure pain before exercise and at peak exercise [18]. A custom-designed questionnaire using a five-point Likert scale (1 = strongly disagree and 5 = strongly agree) was used to assess subjective responses to and following each exercise modality. This was assesed by a telephone call 24 h after the test. Questions included the following: this test was an enjoyable experience; I would perform the same test again; I feel more confident to exercise after this test; I feel like I was able to give a maximal effort; and this test impacted my normal daily activities 24 h later.

All tests were conducted at similar times of the day for each participant. Participants were asked to abstain from cigarette smoking 4 h before, alcohol and caffeinated beverages 12 h before and moderate- or high-intensity physical activity for at least 24 h before each CPET. Participants were reminded to continue taking their normal medications. All tests were overseen by the same experienced researchers and conducted in a climate-controlled room to maintain an appropriate ambient temperature (20–22°C) and humidity (< 60%). Tests were conducted at least 4 days apart, to ensure adequate washout from the previous test.

Before formal analysis, breath-by-breath data were exported via the software package (Quark CPET v1.6.7; COSMED) as a 20-s time average, to reduce the influence of physiological noise [1]. All CPET data analysis was performed independently by two researchers using Excel (Microsoft Corporation, Redmond, WA, USA), who were blinded to exercise modality. Peak CPET values were determined as the maximum 20-s average value for each variable during exercise [1]. Predicted maximal $\dot{V}O_2$ for cycle ergometry was estimated using an equation developed by Jones et al. [19]. Anaerobic threshold was determined using the V-slope method [20], and confirmed using plots of ventilatory equivalents for carbon dioxide ($\dot{V}E/\dot{V}CO_2$) and oxygen, and end-tidal carbon dioxide and end-tidal oxygen, as functions of $\dot{V}O_2$ [1]. The oxygen uptake efficiency slope was defined as the $\dot{V}O_2$ for a given ventilation (slope derived from $\dot{V}O_2$ (y-axis) and the log transformation of minute ventilation (x-axis)) [21]. Predicted maximum heart rate was estimated using the equation published by Tanaka et al. [22]. Where a participant was prescribed a beta-adrenergic blocking agent, an equation in patients with coronary artery disease was used to estimate predicted maximum heart rate [23]; no predictive equations for healthy older adults or individuals with osteoarthritis are available. Prism (v8.0; GraphPad Software, CA, USA) was used for all statistical analysis. A minimum clinical important difference of 2.0 ml.min^{-1}.kg^{-1} was selected based on improved clinical outcomes in prehabilitation studies [24] and its use as a minimal clinically important difference for anaerobic threshold [25]. A sample size of 12 was calculated (nQuerry v 8.5.1.0; Statistical Solutions Ltd., Cork, Ireland) to provide a study power of 85% for detecting a difference of 2.0 ml.min^{-1}.kg^{-1} between any two tests, assuming that the standard deviation of differences was 4.0 ml.min^{-1}.kg^{-1} (based on pilot data) at the 5% significance level. Fifteen participants were recruited to allow for attrition due to the unknown tolerance of the novel exercise modalities in this population. A repeated-measures analysis of variance was used to compare differences in variables across the four exercise modalities and repeated-measures two-way analysis of variance to compare differences in peak $\dot{V}O_2$ by arthroplasty site. Normality and homogeneity of variances were assessed using the D'Agostino-Pearson and Levene's tests. When the assumption of sphericity was violated, Greenhouse-Geisser's adjustment was used. Posthoc testing was performed to compare groups if p values were < 0.05, using Tukey's test to adjust for multiple comparisons. Ordinal data were analysed using the Friedman Test, with Wilcoxon signed rank tests to isolate differences. Differences in within-modality pre-exercise and peak exercise pain scores were compared using a Wilcoxon matched-pairs signed rank test. Inter-rater reliability for

anaerobic threshold was assessed from interclass correlation coefficient, calculated using a two-way mixed model for absolute agreement.

Results

Between January 2019 and July 2019, 18 patients scheduled for total hip or knee arthroplasty were screened prospectively (Fig. 1); 15 patients were included in the analysis and their characteristics are presented in Table 1. No changes in medication type or dosage were reported during the experimental period. No tests were terminated prematurely and symptom-limited maximum values were achieved for all tests. There were no adverse events related to testing.

Peak $\dot{V}O_2$ was higher on treadmill (mean difference (95%CI) 5.8 $ml.min^{-1}.kg^{-1}$ (3.4–8.1); $p < 0.001$), cross-trainer (mean difference (95%CI) 5.5 $ml.min^{-1}.kg^{-1}$ (3.9–7.1); $p < 0.001$) and cycle ergometer (mean difference (95% CI) 3.7 $ml.min^{-1}.kg^{-1}$ (1.8–5.6); $p = 0.001$) modalities, compared with the arm ergometer (Table 2 and Fig. 2). Eight participants recorded their highest peak $\dot{V}O_2$ value on the treadmill, six on the cross-trainer and one on the cycle ergometer. No difference was apparent in peak $\dot{V}O_2$ across modalities between scheduled total hip and knee arthroplasty participants ($p = 0.737$), although the study was not adequately powered for this sub-group analysis.

Peak heart rate was higher on the cross-trainer compared with arm ergometry (mean difference (95%CI) 13 $beats.min^{-1}$ (6-21); $p = 0.005$), but not other modalities (Table 2). Mean (SD) peak heart rates as a percentage of predicted maximum heart rate were 90% (16) for treadmill, 96% (11) for cross-trainer, 92% (11) for cycle and 87% (11) for arm ergometer. Peak respiratory exchange ratio was lower during treadmill testing, compared with cross-trainer (mean difference (95%CI) −0.08 (−0.15 to −0.01); $p = 0.034$) and cycle (−0.09 (−0.15 to −0.03); $p = 0.003$) modalities. Respiratory exchange ratio exceeded 1.10 in one test on the treadmill, four on the cross-trainer, six for the cycle and three for the arm ergometer.

Anaerobic threshold was exceeded on all CPETs, and a very high level of agreement for anaerobic threshold determination was evident between the two blinded researchers (intra-class correlation coefficient (95%CI) 0.93 (0.88-0.96)). Anaerobic threshold was up to 50% higher on the treadmill (mean difference (95%CI) 5.1 $ml.min^{-1}.kg^{-1}$ (3.3–6.9); $p < 0.001$), cross-trainer (6.2 $ml.min^{-1}.kg^{-1}$ (4.8–7.6); $p < 0.001$) and cycle ergometer (2.3 $ml.min^{-1}.kg^{-1}$ (0.8–3.8); $p = 0.003$), compared with the arm ergometer (Table 2 and Fig. 3). The $\dot{V}E/\dot{V}CO_2$ at anaerobic threshold was higher during arm ergometry, compared with the treadmill, cross-trainer and cycle ergometer (Table 2). The oxygen uptake efficiency slope was higher on the treadmill, cross-trainer and cycle ergometer compared with the arm ergometer (Table 2).

Peak exercise pain scores increased from pre-exercise levels for treadmill (median difference (95%CI) 2.0 (0.0–5.0); $p = 0.001$), cross-trainer (3.0 (2.0–4.0); $p = 0.001$) and cycle ergometry (3.0 (1.0–5.0); $p = 0.001$), but not arm ergometry (0.0 (0.0–1.0); $p = 0.406$). Median differences in pre- and peak-exercise pain VAS scores were greater for treadmill (rank sum 42.0 vs. 19.5; $p = 0.009$), cross-trainer (43.5 vs. 19.5; $p = 0.004$) and cycle ergometry (45.0 vs. 19.5; $p = 0.002$), compared with arm ergometry. Participants' perceived ability to give a maximal effort was not significantly different across modalities (Fig. 4; $p = 0.072$). The cross-trainer was more likely to impact normal daily activities in the 24 h following testing, compared with arm ergometry (Fig. 4; $p = 0.043$); however, participants agreed that they would perform the same test again (median (IQR [range]) score 4.0 (2.0-4.0 [1.0–5.0])).

Discussion

This is the first study, to our knowledge, to directly compare CPET variables and subjective responses across four different exercise modalities in patients with severe lower limb osteoarthritis. It is also the first study to describe the physiological and subjective responses of using a cross-trainer for CPET in a clinical population. The main finding was that peak $\dot{V}O_2$ was higher on modalities utilising the osteoarthritis-affected lower limbs (treadmill, cross-trainer and cycle), compared with arm ergometry, which used the upper body only. Specifically, peak $\dot{V}O_2$ values were approximately 20–30% lower with arm ergometry compared with the other three modalities, despite it being the only modality that did not increase peak-exercise pain scores from pre-exercise levels. Anaerobic threshold, another prognostic CPET variable, was approximately 25-50% lower on the arm ergometer compared with the other three modalities. These findings indicate that, despite the presence of severe lower limb osteoarthritis, CPET modalities utilising these joints may provide more representative peak $\dot{V}O_2$ and anaerobic threshold values than arm ergometry.

Peak $\dot{V}O_2$ using arm ergometry is approximately 65-80% of the leg exercise value in healthy individuals [6] and patients with coronary artery disease [7, 8]. The results in this study are similar: the three lower limb modalities elicited higher peak $\dot{V}O_2$ values than arm ergometry despite the lower limb musculoskeletal impediments of patients suffering severe osteoarthritis. Whereas no prior

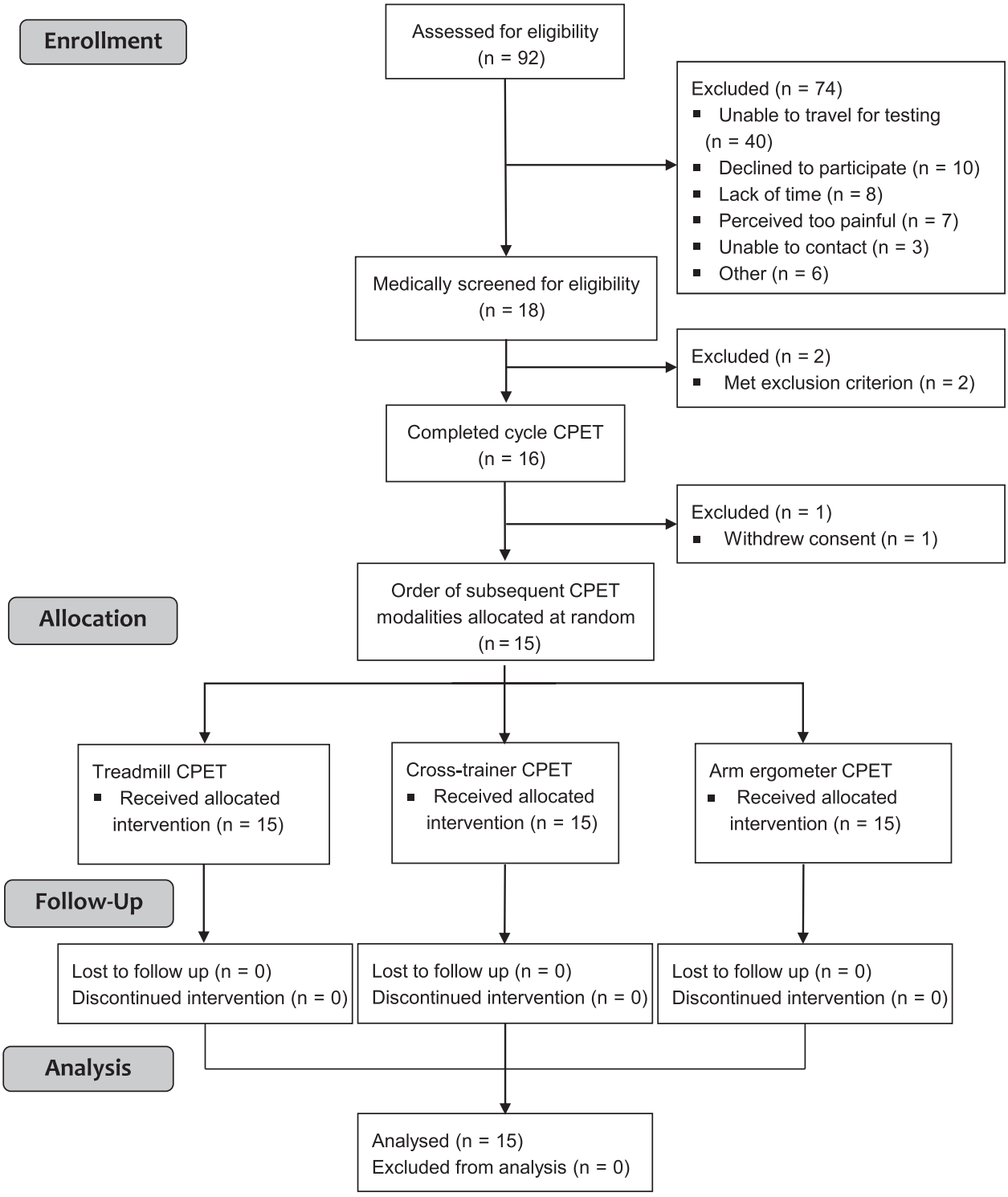

Figure 1 Study flow diagram. CPET, cardiopulmonary exercise test.

comparative data in lower limb osteoarthritis patients have been published, patients with peripheral arterial disease, another cohort characterised by lower limb dysfunction and reduced exercise tolerance, have 25% lower peak $\dot{V}O_2$ and 18% lower anaerobic threshold values during CPET using arm ergometry compared with cycling [9]. One explanation for the consistent discrepancy in peak $\dot{V}O_2$ between modalities is the greater volume of active skeletal muscle

Table 1 Characteristics of participants (n = 15) who completed all four cardiopulmonary exercise tests. Values are mean (SD) or number.

Age; y	68 (7)
Sex; female	10
Height; cm	168 (8)
Body mass; kg	88.6 (12.9)
BMI; $kg.m^{-2}$	31.4 (4.1)
Systolic blood pressure; mmHg	125 (12)
Diastolic blood pressure; mmHg	77 (8)
Heart rate; $beats.min^{-1}$	77 (10)
Predicted peak $\dot{V}O_2$; $ml.min^{-1}.kg^{-1}$	19.9 (4.8)
Arthroplasty site	
Hip	5
Knee	10
Kellgren-Lawrence Score	
Grade 1	–
Grade 2	–
Grade 3	2
Grade 4	13
ASA physical status	
1	–
2	13
3	2
Comorbid conditions	
Obesity	9
Hypertension	8
Dyslipidaemia	7
Asthma	1
Chronic kidney disease	1
Ischaemic heart disease	1
Medication	
Statin	7
NSAID	6
ACE inhibitor	4
Beta-adrenergic blockade	3
Calcium channel blocker	2
Smoking status	
Never smoked	7
Previous smoker	6
Current or quit < 1 year	1
Electronic cigarette	1

$\dot{V}O_2$, oxygen consumption; ASA, American Society of Anaesthesiologists; ACE, angiotensin-converting-enzyme; NSAID, non-steroidal anti-inflammatory drug.

during leg exercise, compared with arm exercise [16, 26]. Other peripheral factors such as a greater proportion and/or earlier recruitment of type-2 muscle fibres [27], which are more susceptible to fatigue, are also likely to contribute to the lower peak $\dot{V}O_2$ and anaerobic threshold values.

Arm ergometry has been shown previously to have clinical utility for the detection of myocardial ischaemia when conventional leg exercise was not feasible [16]. However, for determining anaerobic threshold for pre-operative risk stratification, results from this study show that arm ergometry underestimates anaerobic threshold, from which risk thresholds are often derived, by approximately 25% compared with the cycle ergometer, In a study utilising CPET data to inform postoperative care, Older et al. [28] used an anaerobic threshold < 11 $ml.min^{-1}.kg^{-1}$ to assign patients to the intensive care or high dependency unit as opposed to the general ward. The authors reported excellent predictive power and this threshold has been adopted widely in clinical practice. In the current study, 14 participants had an anaerobic threshold < 11 $ml.min^{-1}.kg^{-1}$ during arm ergometry CPET. Conversely, testing on a treadmill and cross-trainer yielded anaerobic threshold below the prognostic risk threshold for only two participants. If arm ergometry is to be used as a pre-operative CPET risk stratification tool then ergometer-specific thresholds must be established to avoid underestimation of peak $\dot{V}O_2$ and anaerobic threshold which has the potential for additional and possibly unnecessary occupancy in higher care units.

The oxygen uptake efficiency slope and $\dot{V}E/\dot{V}CO_2$ at anaerobic threshold are indices of ventilatory efficiency derived from CPET and do not require maximal effort; this makes them attractive for those unable to obtain maximal cardiopulmonary stress [29]. This study showed that the oxygen uptake efficiency slope differs by exercise modality, with treadmill oxygen uptake efficiency slope approximately 40% higher than with arm ergometry. The oxygen uptake efficiency slope and peak $\dot{V}O_2$ are well correlated, which may explain the higher oxygen uptake efficiency slope for treadmill and cross-trainer compared with cycle and arm ergometry [30]. Similar to the findings of Orr et al. [6], we found that the $\dot{V}E/\dot{V}CO_2$ at anaerobic threshold was up to 11% higher on the arm ergometer compared with the other three modalities. Given that the $\dot{V}E/\dot{V}CO_2$ is used in clinical peri-operative risk stratification, and the oxygen uptake efficiency slope has the potential to be used, clinicians and future research should consider the effect that exercise modality may have on these variables when interpreting results.

The respiratory exchange ratio, an imperfect measure of effort during CPET, was lowest during treadmill testing despite eliciting the highest peak $\dot{V}O_2$. This lower respiratory exchange ratio should not be assumed to reflect

Table 2 Physiological and subjective measures for different modalities of cardiopulmonary exercise tests. Values are mean (SD) or median (IQR [range]). Symbols represent statistically significant between modality post-hoc tests; *p < 0.05 vs. arm ergometer; †p < 0.05 vs. treadmill; ‡;p < 0.05 vs. cycle

	Treadmill n = 15	Cross-trainer n = 15	Cycle n = 15	Arm ergometer n = 15	p value
Peak heart rate; beats.min^{-1}	139 (20)	148 (19)*	143 (19)	135 (17)	0.009
Respiratory exhange ratio at peak exercise	0.98 (0.08)	1.06 (0.10)†	1.07 (0.05)†	1.04 (0.08)	0.004
Relative peak $\dot{V}O_2$; ml.min^{-1}.kg^{-1}	21.5 (4.6)*	21.2 (4.1)*‡;	19.4 (4.2)*	15.7 (3.7)	<0.001
$\dot{V}O_2$ at anaerobic threshold; ml.min^{-1}.kg^{-1}	13.5 (3.1)*	14.6 (3.0)*‡;	10.7 (2.9)* †	8.4 (1.7)	<0.001
$\dot{V}E/\dot{V}CO_2$ at anaerobic threshold	33.8 (4.6)*	34.6 (4.3)*	34.9 (5.6)*	37.9 (4.6)	0.001
Oxygen uptake efficiency slope	2478 (632)*	2233 (699)*‡;	1907 (527)* †	1534 (485)	<0.001
VAS pain score – pre-exercise	1.0 (0.0-4.0 [0.0-6.0])	1.0 (0.0-3.0 [0.0-5.0])	0.0 (0.0-3.0 [0.0-5.0])	1.0 (0.0-4.0 [0.0-7.0])	0.448
VAS pain score – peak exercise	5.0 (3.0-7.0 [0.0-10.0])*	4.0 (4.0-7.0 [0.0-10.0])*	6.0 (2.0-7.0 [0.0-10.0])*	1.0 (0.0-3.0 [0.0-8.0])	<0.001

$\dot{V}O_2$, oxygen consumption; $\dot{V}E/\dot{V}CO_2$, ventilatory equivelant for carbon dioxide; VAS, visual analogue scale.

lack of exertion; previous studies in healthy individuals [31, 32] and patients with peripheral arterial disease [33] have shown similar findings in part due to greater fat oxidation for a given exercise intensity. Peak heart rate is another measure used frequently to determine exercise effort; peak heart rate during treadmill CPET was 90% of predicted maximum substantiating that effort was maximal. Consistent with previous literature, the lowest peak heart rate was observed during arm ergometry compared with the other modalities [5,6]. This is likely due to the earlier peripheral muscle fatigue associated with arm ergometry [16].

The cross-trainer provided consistent and reliable readings across monitored variables. Peak-exercise pain scores and ability to give a maximal effort were not different on the cross-trainer compared with the other lower limb modalities. Additionally, unlike the treadmill, the cross-trainer allows accurate quantification of work rate, making it a viable CPET modality in patients with severe osteoarthritis.

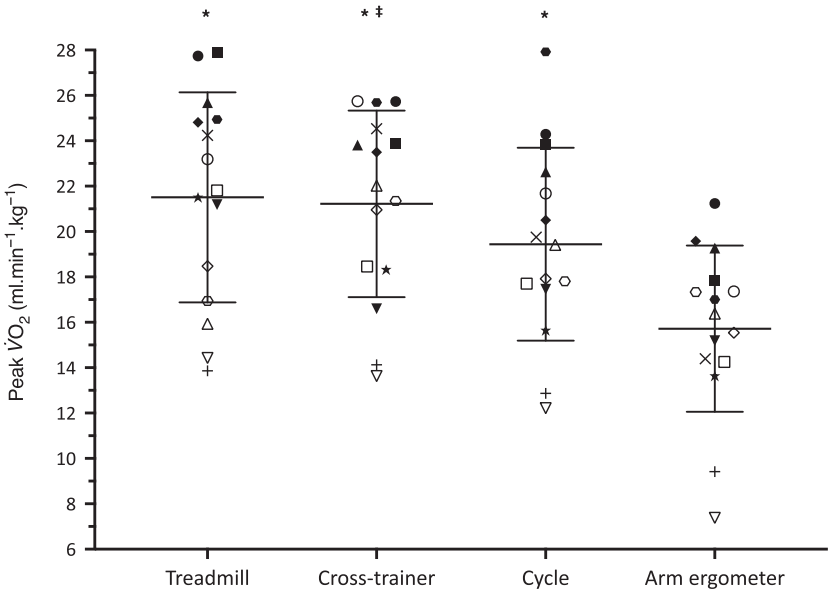

Figure 2 Peak oxygen consumption ($\dot{V}O_2$) by cardiopulmonary exercise test (CPET) modality. Results from individual participants (each symbol represents an individual participant's peak $\dot{V}O_2$ across the four modalities) and mean (error bars indicate SD) are presented for each CPET modality. *p < 0.05 vs. arm ergometer; ‡p < 0.05 vs. cycle). n = 15 for all.

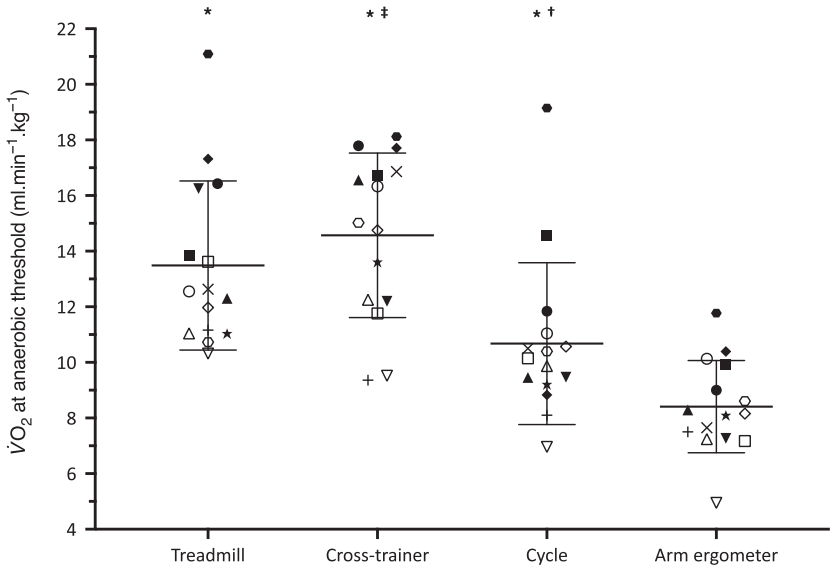

Figure 3 Anaerobic threshold by cardiopulmonary exercise test (CPET) modality. Results from individual participants (each symbol represents an individual participant's anaerobic threshold across the four modalities) and mean (error bars indicate SD) are presented for each CPET modality. *p < 0.05 vs. arm ergometer; †p < 0.05 vs. treadmill; ‡;p < 0.05 vs. cycle). n = 15 for all.

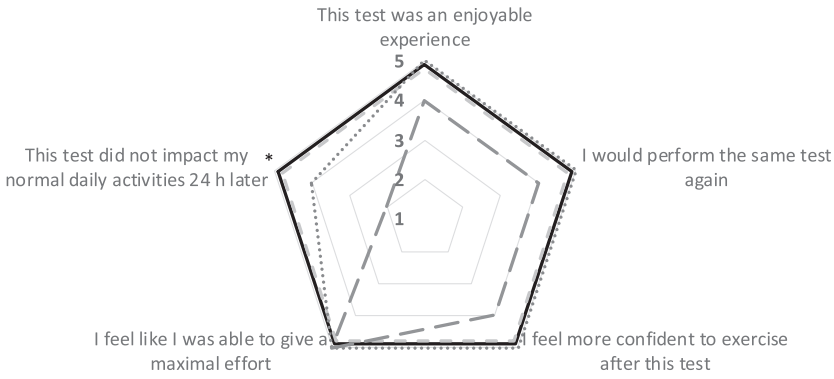

Figure 4 Radar plot showing subjective acceptability questionnaire responses by cardiopulmonary exercise test modality (1 = strongly disagree, 5 = strongly agree). Data are median; *p < 0.05 cross-trainer vs. arm ergometer. n = 15 for all. Grey dotted line - treadmill; dark grey dashed line - cross-trainer; grey dashed line - cycle; black solid line – arm ergometer.

A greater active skeletal muscle mass, due to the weight-bearing nature and concurrent use of the upper body, is likely to contribute to a higher peak $\dot{V}O_2$ compared with cycle ergometry. Its utility should be explored in other clinical cohorts.

A limitation of the study design was that the initial CPET served as screening for underlying cardiovascular disease, so all initial testing was performed on the cycle ergometer to ensure a reliable ECG trace could be obtained. However, only one participant achieved their highest peak $\dot{V}O_2$ on the cycle, suggesting no order effect. Despite typical age, Kellgren-Lawrence grade and ASA physical status, the present cohort may not be reflective of all patients scheduled for total hip or knee arthroplasty due to mean peak $\dot{V}O_2$ values being higher than those reported previously [5]. Therefore, future studies with larger sample sizes are necessary to validate findings in this study, in order to compare different populations with osteoarthritis, and define risk thresholds and peri-operative prognostic criteria for alternative CPET modalities.

In conclusion, despite the presence of lower limb osteoarthritis and higher peak exercise pain scores, peak $\dot{V}O_2$ and anaerobic threshold values were higher during CPET on modalities utilising these joints (treadmill, cross-

trainer and cycle), compared with arm ergometry. Whereas arm ergometry may have pre-operative utility for detecting underlying cardiopulmonary limitation, peak $\dot{V}O_2$ and anaerobic threshold values should not be used for risk stratification, unless modality specific thresholds are created. Treadmill, cross-trainer and cycle modalities are feasible and may provide more representative peak $\dot{V}O_2$ and anaerobic threshold values, when compared with arm ergometry. In a clinical setting, any one of these primarily lower limb modalities would be appropriate to use.

Acknowledgements

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ORIGINAL ARTICLE

RADIATION USE IN THE ORTHOPAEDIC THEATRE: A PROSPECTIVE AUDIT

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Background: There is concern about the exposure of orthopaedic surgeons to radiation. The aim of this study was to monitor radiation use in theatre to improve practice and to attempt to quantify the radiation dose the orthopaedic surgeon may have received.
Methods: A 6-month prospective audit of all procedures performed in the orthopaedic theatre that used fluoroscopy or radiographs was undertaken An anthropomorphic phantom was used to measure scatter and direct-skin doses. Screening times were recorded in a subsequent 6-month post at a tertiary trauma centre.
Results: Fluoroscopy or radiographs were used in 378 procedures. Fluoroscopy was used in 260 procedures with a screening time of 124 min at an average of 0.48 min per procedure. Lead aprons were worn in 99% of cases and thyroid guards in 32%. All dosimeter badges were negative. The surgeon's hand was caught in the fluoroscopy beam in 15% of procedures. The phantom recordings ranged from 13 to 210 microGy for skin dose and 0.17–0.87 microGy for scatter dose. The calculated hand exposure was less than 5% of recommended levels. In the trauma post 210 min of screening was used potentially increasing the hand exposure to one-third of recommended limits. If a printer was used to record the image, 58% of intra-operative radiographs would have been avoided.
Conclusions: Hand exposure to radiation is the limiting factor in orthopaedics. The extremity limit will only be exceeded if the hands are regularly caught in the beam. Dose-reduction gloves should be considered for high-risk procedures. A printer can reduce the need for intraoperative plain radiographs.

Key words: exposure, ionizing radiation, orthopaedics, radiological protection.

INTRODUCTION

The use of fluoroscopy has increased over the last 20 years especially in the orthopaedic trauma theatre. A key principle of the use of ionizing radiation is to keep the dose as low as reasonably achievable (ALARA).[1] Since 1991, the risk estimates for low-dose radiation have been re-evaluated and increased six-fold. This has led to a reduction in dose limits to radiation workers from a 50 mSv/year to a 20 mSv/year whole-body dose.[2] Studies have suggested that orthopaedic surgeons are not exposed to excessive levels of radiation unless 750 intramedullary roddings per year are performed.[3] However, there may only be a four-fold safety factor for hand exposure.[4]

The purpose of our study was to prospectively audit the use of radiation in the orthopaedic theatre, to attempt to assess the exposure of the operating surgeon to radiation and to identify methods to improve practice and reduce radiation usage.

METHODS

A 6-month prospective audit was conducted of all procedures performed by orthopaedic registrars or consultants which required the use of radiographs or the image intensifier in theatre. Our institution is a general hospital with a steady trauma workload. There are six consultants and four registrars.

A form was completed at the time of surgery noting the surgeon, case details, what protection was worn, screening time, number of hard copies taken and the perceived need for those films and whether the surgeon's hand was caught in the X-ray beam during the case, which was termed a critical incident.

A series of measurements were then made using the Philips BV 25 image intensifier (Philips Medical Systems, Auckland, NZ), a Rando anthropomorphic phantom (The Phantom Lab Inc., Salem, NY, USA), a Capintec 192 dose meter and a Capintec PM-30 ionization chamber (Capintec Inc., Ramsey, NJ, USA). Measurements were taken with the dose meter positioned to simulate the position of the surgeon's hands during common procedures. Skin and scatter doses were measured. The direct dose to the hands of each registrar was then calculated from the reported number of critical incidents multiplied by the skin dose recorded. The scatter dose was estimated by assuming that the hands were at the closest point to the beam throughout the recorded screening time. This gives a maximum possible scatter dose. Standard X-ray film badges were worn for 2 months of the study period both under the lead apron and on the dominant shoulder outside the apron. These were read by the New Zealand National Radiation Laboratory.

For the next 6-month period the screening times of the first author (DGJ) were reviewed during a trauma registrar post at a tertiary trauma referral centre.

RESULTS

A total of 378 procedures required the use of X-rays: radiographs were taken during 118 procedures and fluoroscopy was used in 260 procedures (Table 1). Four registrars performed 240 (92%) of these procedures.The orthopaedic experience of the registrars ranged from 1 to 4 years. Six consultants performed the remaining 20 procedures. A total of 124 min screening was used during the 6-month period. The average total screening time for the

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Table 1. Operative procedures that use fluoroscopy

Procedure	No.	Average screening time (min)	Procedures with critical incidents No. (%)
Manipulations	98	0.1	8 (8)
Hip fixation	55	0.6	2 (4)
Intramedullary rods	39	2.1	17 (44)
K-wire hand	34	0.3	10 (29)
Internal fixation	22	0.5	1 (5)
Others	12	0.5	1 (8)
Total	260	0.48	39 (15)

Table 2. Fluoroscopy screening times, critical incidents and estimated radiation exposure by operating surgeon for 6-month study period

Surgeon	Cases	Screening time (mins) Average	Total	Critical incidents	Procedures with incident No. (%)	Estimated exposure Direct	Scatter (mSv)	Total
Reg 1	76	0.43	32.8	17	10 (13)	1.7	1.0	2.7
Reg 2	63	0.61	38.2	33	18 (29)	2.5	1.5	4
Reg 3	49	0.55	27.1	9	4 (8)	0.3	1.0	1.3
Reg 4	52	0.33	17.3	9	6 (12)	0.6	0.4	1.0
Con (6)	20	0.44	8.8	1	1 (5)	< 0.1	0.3	< 0.1
Total	260	0.48	124.2	69	39 (15)	5.1	4.2	9.0

Reg, registrar; Con, consultant.

Table 3. Hand radiation exposure with fluoroscopy from anthropomorphic phantom recordings

Procedure	Distance from beam	Skin dose (microGy)	Scatter dose (microGy)	Scatter : skin ratio (%)
PA hip	30 cm	210	0.19	0.09
Lateral hip	30 cm	105	0.26	0.25
Distal locking	15 cm	125	0.87	0.7
	30 cm	125	0.41	0.3
Forearm	Just out of view	12.9	0.17	1.4

PA, postero–anterior.

registrars was 28.9 min (range 17.3–38.2 min) (Table 2). The average screening time for each procedure was 0.48 min.

In 99% of fluoroscopy procedures a lead apron was worn. A thyroid guard was worn in 32% and lead gloves in 2% of fluoroscopy procedures. Lead glasses were not available.

All the dosimeters worn inside and outside the lead aprons were negative during the trial period, which indicated levels lower than 0.15 mSv.

Critical incidents were reported on 69 occasions and occurred in 39 procedures that used fluoroscopy (15%) (Table 1). These most commonly occurred during intramedullary rod fixation and K-wire fixation in the hand. Distal locking was the cause given for 30% of critical incidents, carelessness or radiographer error for 30% and holding a hand or arm for 40%. The reported rate of procedures with critical incidents for individual registrars ranged from 5 to 29% of procedures that used fluoroscopy (Table 2).

Radiation recordings were made using the anthropomorphic phantom (Table 3). The highest skin dose recorded was for a PA of the hip (210 microGy). The lowest was for a forearm (12.9 microGy). The scatter dose was highest during distal locking using a 15-cm trocar (0.87 microGy). Hand positions for the other procedures recorded scatter levels from 0.17 to 0.26 microGy. The ratio of scatter to skin dose ranged from 0.09 to 1.4%, which varied with the distance of the recorder from the beam. The estimated maximum possible absorbed dose to the hand for each registrar ranged from 2 mSv to 8 mSv per year.

In 190 of the 260 procedures that used fluoroscopy (70%), plain films were also taken. In 182 of these 190 procedures (96%), the film was taken with the cassette placed on the image intensifier. In six cases (3%), intra-operative radiographs resulted in the procedure being revised. In 110 of these 190 procedures (58%), the plain radiographs were felt to be unnecessary had there been a printer available to copy the on-screen images. More than two films were taken on 25 occasions; 11 were required because of technical errors. Two hundred and twenty-three films could have been avoided in the theatre.

During the subsequent 6 months one of the authors (DGJ) performed 138 procedures using fluoroscopy with a screening time of 210 min, giving an average screening time of 1.5 min per case.

DISCUSSION

A number of studies have looked at the exposure of the orthopaedic surgeon to radiation.[2–9] All have concluded that the whole body dose received is well within the recommended levels but have emphasized caution due to the uncertainty of long-term effects of low-dose radiation. In the present study the finding of negative radiation badges supports this view. Exposure of the hands has been

shown to be the limiting factor in orthopaedics,[3,4,9] whereas in cardiological practice it is the lens of the eye.[10] Fortunately the hand is relatively insensitive to radiation with an annual extremity dose limit of 150 mSv for non-radiation workers.[11] In New Zealand, orthopaedic surgeons are presumed to be radiation workers and therefore the annual extremity dose limit is 500 mSv.[12] Our results show that there is a safety factor of approximately 20-fold for hand exposure based on the International Commission on Radiological Protection (IRCP) figure. However, during a busy trauma run there may be a seven-fold increase in screening time, which could reduce the safety factor to three-fold. The authors of the present study agree with Smith that routine monitoring with film badges under or outside the apron will not adequately assess the extremity dose, which is the limiting factor.[9]

To our knowledge, this study is the first to specifically record critical incidents, which depends on the surgeon reporting them, and we suspect that they are under-reported in our series. However, they are still surprisingly common and occur in an average of 15% of procedures using fluoroscopy. With care they should all be avoidable. In order to approach the ICRP limit of 12.5 mSv per month it would take at least 240 min of scatter radiation or 1 min of direct exposure, i.e. 60 incidents each month. Our measurements suggest that direct exposure must have occurred in those series where thermoluminescent dosimeter (TLD) rings were used to record hand exposure.[3,4,9]

Under the Euratom directive,[1] it is mandatory that radiation training is given to all staff who use radiation for medical procedures. In New Zealand, this is the responsibility of the licensee for an institution.[12] Little or no formal training is given to orthopaedic surgeons. Guidelines for safe use of radiation in the orthopaedic theatre have been published.[2–5,7,8] The image intensifier should be positioned as close to the patient as possible to reduce back scatter and allow decreased doses to be used. The equipment should have a memory facility and be serviced regularly. Live fluoroscopy should be avoided if possible. In the present study, lead aprons were almost always used, and the surgeon retired whenever possible. Thyroid guards could be used more regularly. Sterile radiation reduction gloves would be useful especially for hand cases and distal locking of intramedullary rods when the hands are very close to the beam and critical incidents are common. However, they will not protect the hands from direct exposure. A comparison of the screening times for similar procedures from the two study periods suggests that monitoring of screening times helps to reduce the amount of radiation used.

We estimated that at least 58% of our intra-operative radiographs could have been avoided if a printer had been available to record the on-screen image. This is in agreement with Williams *et al.*,[13] who found that thermal prints could replace radiographs in 75% of cases. Pattison *et al.* showed that thermal prints were a satisfactory and cost-effective alternative to postoperative hip radiographs which reduce the patient dose by 5–6 cGy.[14] The amount of radiation used in a plain radiograph is approximately 10 times that of a single-image intensifier flash. Therefore there is potential for a significant reduction in radiation dose to the patient.

CONCLUSIONS

Although radiation exposure to orthopaedic surgeons is within recommended levels, there should be no complacency because of the uncertainty in predicting the effects of low-dose radiation. There is no safe dose of radiation and the ALARA principle should be observed for both the patient and surgeon.[2,15]

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Radiation Exposure During Fluoroscopically Assisted Pedicle Screw Insertion in the Lumbar Spine

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Study Design. An experimental model to assess radiation exposure during lumbar pedicle screw insertion.

Objectives. To measure skin (patient) and scatter (surgeon) doses of radiation during lumbar spine fluoroscopy to assess safety of the procedure for both the surgeon and patient and determine best practice.

Summary of Background Data. Fluoroscopy assists with accuracy of pedicle screw placement, yet the optimal technique of C-arm use and risk to both patient and operating room staff from radiation exposure are unknown.

Methods. Entry- and scatter-dose recordings were made using a digital dosimeter while screening an anthropomorphic phantom prone on a radiolucent operating table. The source was positioned both superiorly and inferiorly with the height varied in the latter orientation to create a working space under the C-arm. The senior author's fluoroscopy records were reviewed in 140 consecutive cases.

Results. In a series of 140 patients who underwent pedicle screw fixation, the fluoroscopy time was 1.4 minutes per case or 0.33 minutes per screw. In the source-superior position, the effective dose received by the patient was approximately 2.3 mSv per case. In the source-inferior position with a working space of 300 mm, the effective dose was 6.8 mSv. Scatter dose to the surgeon was higher in the source-superior position but was still less than 10% of recommended limits for the hand, thyroid, and eyes.

Conclusions. The source-superior position is the preferred position for pedicle screw screening if a working space is required. Patient exposure is minimized, and surgeon dose is well within current recommendations. [Key words: fluoroscopy, lumbosacral region, radiation protection, spinal fusion] **Spine 2000;25:1538–1541**

Pedicle screws are now routinely used during instrumentation of the lumbar spine. Despite their accepted advantages, the potential complications from their misplacement remain a serious concern. The nerve root is particularly at risk as it passes around the pedicle. Higher rates of reported pedicle screw misplacement have ranged up to 40%.[1,4,6,11,14] Fluoroscopy is widely used to assist placement of the pedicle screws, yet the optimal technique of image intensifier use and the risk of radiation exposure to the patient and operating room staff are not known.

Ionizing radiation has been increasingly used in orthopedic surgery, especially in the trauma theater. In 1991 the estimate of the risk from exposure to low-dose ionizing radiation was increased six times.[7] In a recent report, the results have indicated an increased incidence of thyroid malignancies among orthopedic surgeons.[2] Results in other studies have shown that the surgeon's hand is most at risk.[5,12]

The purpose of the current study was to determine the optimal technique of image intensifier use by measuring skin and scatter doses of radiation during screening of the lumbar spine and to assess the safety of this procedure to both the surgeon and patient.

Methods and Materials

An anthropomorphic phantom (Rando; Radiology Support Devices, Long Beach, CA), which is designed to simulate a 70-kg patient, was placed prone on a radiolucent operating table with pillows under the phantom to reproduce the position used for posterior lumbar spinal surgery.

Fluoroscopy of L4 was then performed using an image intensifier (BV25 Gold; Phillips BV, Eindhoven, The Netherlands). The fluoroscope was positioned coaxial to the pedicles with the source superior and the image intensifier under and as close to the table as possible (source-superior position, beam directed down, posteroanterior screening). Measurements of radiation were then taken within the beam and at horizontal positions to a distance of 1 m. Measurements were also taken at the level of the phantom and vertically above and below the phantom to simulate the organs of the surgeon at risk, if the surgeon were standing adjacent to the operating table.

The fluoroscope was then reversed so that the source was inferior (source-inferior, beam directed up, anteroposterior screening). Readings were repeated with the image intensifier (receiver) at various heights above the phantom, to create a working space.

Readings were taken with a digital dosimeter (Model 35055; Keithley Instruments, Cleveland, OH) using a 15-mL ionization chamber for primary beam measurements and a 900-mL chamber for scatter measurements.

The screening times for all pedicle screws inserted by the senior author (PAR) during a 4-year period were used to calculate relative risk estimates of radiation exposure to the hand, eyes, and thyroid based on the guidelines of the International Commission for Radiologic Protection (ICRP).[8] The effective dose received by the patient was calculated from the estimated entry dose, by using tabulated results of doses to organs for given peak kilovolts (kV), filtration, beam orientation and body part, by the National Radiation Laboratory.

Results

The exposure factors used were 75 kV(p) and 2.7 mA with an exposure time of approximately 1 second to

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Device status category: 1.
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Table 1. Dosemeter Readings Taken With Source Superior and Source Inferior (Allowing a Working Space of 30 cm Between the Image Intensifier/Receiver and the Patient). Values for Organ Dosage are for Measurements 20–25 cm From the Beam, Simulating the Surgeon Standing Adjacent to the Operating Table

	Source Superior microGy/image	Source Inferior (30 cm) microGy/image	Ratio of Dosage Superior:Inferior
In beam	508	3.65	139
5 cm away	10	0.6	17
20 cm away	2.4	0.32	7.6
25 cm away	1.3	0.28	4.6
50 cm away	0.15	0.14	1.1
Knees	0.06	0.65	0.09
Gonads	0.49	1.4	0.35
Eyes	0.56	0.04	13
Thyroid	0.81	0.06	14

obtain adequate images of the pedicles in the phantom, which simulates a 70-kg man.

Radiation doses for the source-superior and source-inferior positions at varied distances to simulate hand positions and varied heights for radiosensitive organs are tabulated in Table 1 and demonstrated in Figures 1A and 1B. There is an exponential decrease in scatter radiation with increasing distance from the beam.

In the source-inferior position with the image intensifier 33 cm above the back, allowing the maximum working area, the entry dose for the phantom was 1433 μGy/image, which is almost three times higher than that in the source-superior position. This decreased to 756 μGy when the image intensifier was 30 cm and down to 508 μGy when the image intensifier was 20 cm above the back.

The scatter doses to the hand, thyroid, and eyes in the source-inferior position (Image Intensifier 30 cm above) are much lower (6–13% of the source-superior position). The direct beam measurement is 139 times higher in the source-superior position. The gonad dose and knee doses are higher by a factor of 3 and 11, respectively, in the source-inferior position.

In a 4-year period, the senior author performed 140 operations on the lumbar and lumbosacral spine involving pedicle screw fixation. Six hundred twenty-six screws were inserted with a total screening time of 208 minutes, with a mean screening time of 1.4 minutes per case (range, 0.6–3.5 minutes) or 0.33 minutes per screw. Screening was performed in the coaxial plane with the source superior with confirmatory lateral views taken at completion with the C-arm over the table. No record was made of whether the hand was caught in the beam. There was no clinical or radiographic evidence of screw malposition or nerve root damage due to pedicle screw placement.[9]

Based on 50 minutes of screening during 34 cases a year this gives a maximal scatter dose to the hands of 31 mSv/yr assuming that the hands are within 5 cm throughout screening. Direct exposure would add 0.5 mSv for each occasion the hand is caught. The thyroid dose if no shield were used would be 2.4 mSv/yr and the eye dose 1.67 mSv/yr, based on the scatter recordings in the source-superior position.

Based on ICRP recommendations,[8] performing 50 operations per year would give a safety factor of 11-fold for hands, 117-fold for thyroid, and 63-fold for eyes.

The entry dose to the patient would average 43 mSv/case (range, 18–107 mSv) assuming the average screening time of 1.4 minutes in the source-superior position. The effective dose to the whole body can be calculated from the entrance dose to the lumbar spine region by using tabulated results of peak kilovolts, filtration, and beam orientation. The effective dose per entry dose for trunk irradiations is, in general, two times higher for anteroposterior projections than for posteroanterior projections of the same body part. For the source-superior (posteroanterior) position, the effective dose is 2.3 mSv (range, 1–5.75 mSv). For comparison, the approximate effective dose of a single anteroposterior lumbar spine radiograph is 0.5–1 mSv. Extrapolating to the source-inferior (anteroposterior) positions the average effective dose would increase to 6.9 mSv when the C-arm is set up with 30 cm of working space between the image intensifier and the patient.

■ Discussion

Although fluoroscopy has been recommended to aid pedicle screw placement in the lumbar spine, details of the technique in the literature are vague. Diagrams showing the image intensifier in the source-inferior position have been published.[10,13] The senior author has used the source-superior position, because there is an approximately 46-cm space available for the instrumentation of the spine. The source is less bulky than the image intensifier. This allows use of conventional probes and drills

Table 2. Patient Entry and Effective Dose With Various Fluoroscope Positions

Position		Dose (microGy/image)	Average/Case* Entry	Effective
				(mSv)
Source superior		508	43	2.3
Source inferior Image intensifier	33 cm above back	1433	120	12.8
	30 cm	756	64	6.9
	20 cm	508	43	4.6

* Calculated from 1.4 mins screening time per case.

Table 3. Comparison Between Extrapolated Exposure and ICRP Recommended Safety Levels

	Recommended Level ICRP (mSv/yr)	Extrapolated Level (50 mins screening/yr, 34 cases) mSv/yr	Safety Factor for 34 cases/yr	50 cases/yr
Hand	500	31	16	11
Eyes	150	1.67	90	63
Thyroid*	20 (effective dose)	0.12 (effective dose)	167	117

* Thyroid limit based on assumption that thyroid is the only radiosensitive organ exposed if lead apron worn. Therefore, limit is effective dose limit multiplied by thyroid weighting factor of 0.05.
ICRP = International Commission For Radiologic Protection.

during screw placement while having the facility to repeatedly spot screen throughout insertion. The entry dose to the patient is approximately 2.5 times that of posteroanterior hip screening during hip fracture fixation. The effective dose to the patient with the average screening time in the source-superior position equates to approximately three to four times that of anteroposterior lumbar spine radiographs.

From a pure radiation protection perspective the source-inferior position, with the image intensifier as close to the back as possible, is the ideal. There is less magnification of the image and most of the scatter is directed downward, away from the operator's trunk and head. This would be a preferable way to check final position. However, if a working space is created, then the patient entrance, and therefore the effective dose, increases unacceptably. With 30 cm of working space, the entrance dose is increased by half again and the effective dose by threefold because of the anteroposterior projection.

In the source-superior position, the calculated scatter doses to the thyroid and eye are only 0.8% and 1.6% of recommended levels, respectively. However, care should be taken to shield the thyroid and the eyes during screening. The hand exposure calculated using the source-superior position is only 9% of ICRP recommendations. There is little risk of exceeding these limits unless the hand is regularly caught in the radiograph beam. Keeping the hands at the edge of the torso reduces scatter dose by a quarter compared with the dose within 5 cm of the beam. Modified instrumentation may help this.

The scatter exposure to the hands, thyroid, and eyes and direct exposure to the hands is greatly reduced in the source-inferior position. However, optimum safe practice must take into account the dose to the patient. It is a key principle of the safe use of ionizing radiation to keep the radiation dose to the patient and surgeon as low as reasonably achievable, consistent with good surgical practice.[3]

■ Conclusions

The results in this study show that patient radiation exposure is greater in the source-inferior position than in the source-superior position when a working space is created. Patient entry dose and magnification can be reduced by having the image intensifier as close to the dor-

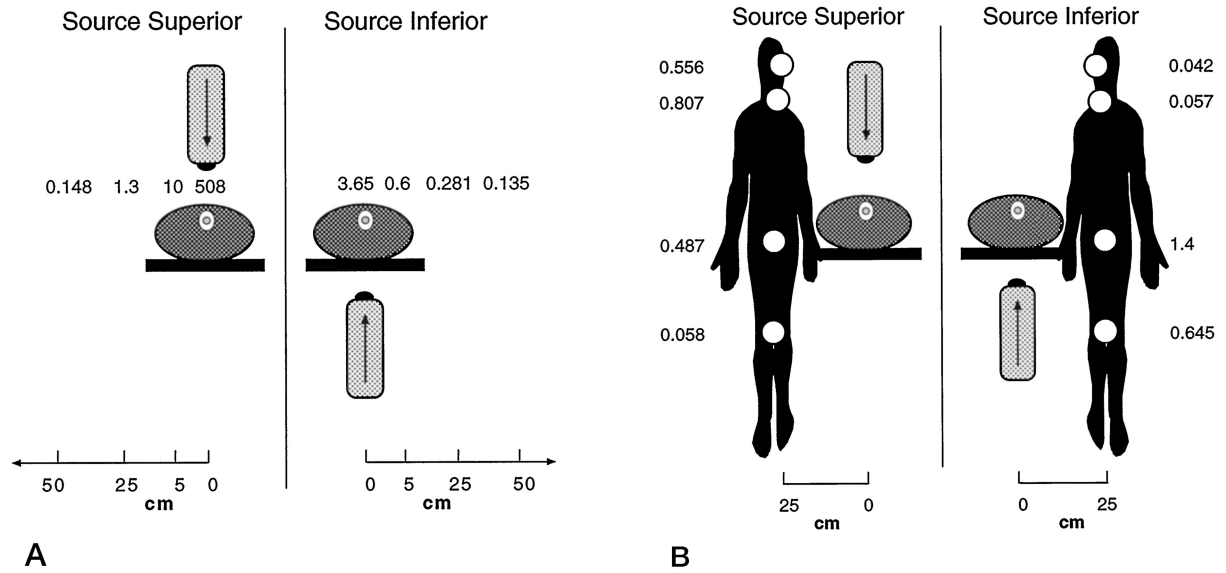

Figure 1. **A,** diagrammatic representation of dosimeter readings (in microguys per image) in, and at increasing distances from, the C-arm beam in the source-superior and source-inferior positions (30 cm working space between the image intensifier and the patient in the source-inferior position). Note that only the source is illustrated. The image intensifier is not demonstrated in the figure. **B,** Readings at the levels of the eyes, thyroid, gonads, and knees are demonstrated. These readings are taken 20–25 cm from the beam, as though the surgeon were adjacent to the operating table.

sal surface as possible in the source-inferior position. Dosage to the surgeon is greater in the source-superior position, yet it is well within current threshold limits if accidental beam exposure is avoided. Current instrumentation could be modified to allow the hands to remain outside the critical 5-cm radius, and preferably outside 20 cm. Surgeons are advised to keep their hands as far from the beam as possible and to limit screening time. A lead apron must be worn, and a thyroid shield and protective glasses should be worn.

■ Key Points

- Fluoroscopic screening with source superior to the patient minimizes the patient's effective dose.
- Scatter radiation to the surgeon is higher in the source-superior position but is still well within recommended levels.
- The surgeon's hands should be kept lateral to the torso during screening to reduce scatter, and the surgeon must avoid direct exposure to the radiation beam.
- Adequate radiation protection must be worn by the operating team.

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Reprints will not be available.

Chapter 7
Results of surgical treatment: 'Getting it right first time' and improving the outcomes of surgery.

By improving the outcomes of surgery and reducing complications there can be significant savings in both time and money. This is particularly relevant for THR and TKR when surgery is usually highly successful but complications such as deep infection and dislocation can be very difficult and expensive to manage. Not all implants perform equally as well at longer term follow up. National Joint registries have been developed that allow poorly functioning implants to be identified early and can also be used to identify outlier surgeons. Revision hip and knee surgery can be complex and have a major impact on patients. It also uses up precious resources that could be used for primary elective surgery. The 'Getting it right first time programme (GIRFT)' in the UK looked at all aspects of surgical management including appropriate implant choice. By avoiding early and late complications it improved efficiency and outcomes.

This chapter includes cohort studies on the outcomes of THR and TKR that include patient reported functional results and long-term results. An important focus in TKR is improving function both through prosthesis design and surgical technique. '*The effect of sagittal laxity on function following posterior cruciate retaining total knee replacement*' considers this issue.

In the early 1990s we started using uncemented components for THR more frequently. Our two papers '*The Morscher Press Fit acetabular component: A 9 to 13 year review'* and '*The Morscher Press-Fit Acetabular Component: An Independent Long-Term Review at 18-22 Years'* showed excellent survival of this uncemented monoblock design at long term. However, a desire to follow evidence coupled with a management imperative to reduce implant costs led to the department instituting a cement only policy in our public hospital in the late 1990s. We became aware that cemented cups were failing at 10-15 years while uncemented cups performed prior to this policy change or performed at our private hospital were continuing to do well. This led to two studies '*Hybrid Fixation for Total Hip Arthroplasty Showed Improved Survival Over Cemented and Uncemented Fixation' and 'Cemented or cementless acetabular fixation in combination with the Exeter Universal cemented stem.'* In these we have shown that uncemented acetabular components, especially those of monoblock design, and hybrid fixation in THR is associated with excellent long-term survivorship surpassing that of all cemented THR. This is in contrast to published results and registry data. Our results support the trend away from using cemented acetabular fixation that has occurred worldwide. These papers help inform decisions regarding implant choice and fixation at the time of primary surgery that may reduce the future revision burden. We have less evidence to support uncemented femoral fixation but have also used it for many years. Our case report *'Bilateral uncemented total hip arthroplasty in osteopetrosis'* was the first long term report of the use of uncemented components in this rare condition and is regularly cited.

Complications can occur despite good surgical technique. '*Polyethylene liner dissociation with the Pinnacle acetabular component: Should we be concerned?*' is an example of an uncommon problem identified locally but not apparent from registry data possibly due to

lack of specific fields in the reporting template. The follow up paper '*Acetabular liner dissociation: A comparative study of two contemporary uncemented acetabular components'* concludes that this is more likely to be an implant specific problem rather than a feature of similar 3rd generation modular systems.

The papers in this and preceding chapters report results that match or surpass those of major international centres. They highlight both the quality of our service over many years and the importance of local research and audit.

The Effect of Sagittal Laxity on Function After Posterior Cruciate–Retaining Total Knee Arthroplasty

David P. Gwynne Jones, MA, FRCS FRACS (Orth), Conlin Locke, MB BCh, Jonathon Pennington, MB ChB, and Jean-Claude Theis, MCh, FRACS (Orth)

Abstract: We studied sagittal laxity using the KT1000 arthrometer in 97 total knee arthroplasties (TKAs) in 83 patients using the porous-coated anatomic knee or Duracon TKA (Howmedica, Rutherford, NJ) with 5.4- to 9.9-year follow-up. Two differing tibial inserts were used: flat (group 1) and anteroposterior (AP) lipped (group 2). Greater posterior and total laxity at 75° was seen in group 2 despite the AP-lipped insert. No differences were seen in functional outcome scores between groups. No significant relationship was seen between laxity and functional outcome. Knees with more than 10 mm of AP laxity at 75° had significantly less flexion and lower Knee Society Scores than knees with 5 to 10 mm of AP laxity. We conclude that the optimal sagittal laxity in this cruciate-retaining TKA is between 5 and 10 mm, although this may not hold for posterior-stabilized designs. **Key words:** total knee arthroplasty, posterior cruciate retaining, sagittal laxity, KT1000 arthrometer.

It is not clear how much sagittal laxity is acceptable after total knee arthroplasty (TKA). Moderate laxity may give a better range of motion (ROM) and improved functional results compared with a knee that is too tight [1,2]. However, too much laxity may lead to instability, poor function, pain, and early failure [3-5]. Total anteroposterior (AP) laxity of 5 to 10 mm appears to give satisfactory results [1,3,6-9]. Greater than 10 mm may have worse function [3], but less than 5 mm has an increased risk for a fixed flexion deformity (FFD) [1]. Factors that may influence the sagittal laxity after a cruciate-retaining TKA include the functional status of the posterior cruciate ligament (PCL), the geometry of the prosthesis, and bone cuts including the posterior tibial slope.

The aims of the study were to determine whether sagittal laxity has an effect on functional outcome and ROM after posterior cruciate–retaining (PCR) TKA and whether 2 differing PCR tibial inserts, 1 relatively flat to allow femoral "rollback" and 1 with an anterior and posterior lip to give greater conformity, used with the same femoral component had an effect on laxity or functional outcome.

Materials and Methods

We reviewed 83 patients with 97 knee arthroplasties using the porous-coated anatomic (PCA) or Duracon TKA (Howmedica, Rutherford, NJ) performed between January 1992 and December 1996 at Dunedin Public Hospital. These were performed by 7 orthopedic surgeons and supervised registrars. The femoral component is asymmetric with a curved

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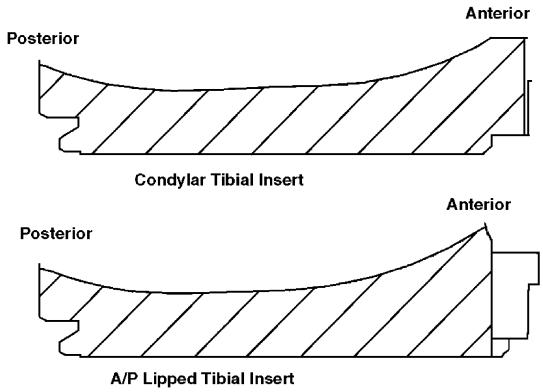

Fig. 1. Cross-sectional diagram of the PCA condylar tibial insert (group 1) and AP-lipped insert (group 2).

"patella-friendly" intercondylar groove and curved distal femoral condyles. There were no significant changes made to the femoral design during the study period. Two differing tibial insert designs were used (Fig. 1). A relatively flat design that allows femoral rollback was used between 1992 and 1993 in the PCA knees. An AP-lipped insert was introduced in late 1993 and used for the rest of the study period in the Duracon knees. This has an elevated anterior and posterior lip, and more conforming geometry. Both are designed to be implanted with PCL retention. Patellae were replaced on an individual basis in 36% of the knees. The minimum follow-up was 5 years. No knee arthroplasties from the study period were revised for instability.

Group 1 (flat insert) consisted of 51 knees in 44 patients. There were 25 males and 19 females. The average age at operation was 71.1 ± 6.4 years with an average follow-up of 8.0 ± 1.0 years (range, 6.8-9.9 years).

Group 2 (AP-lipped insert) consisted of 46 knees in 44 patients, also 25 males and 19 females. The average age at operation was 69.1 ± 6.1 years with an average follow-up of 6.1 ± 0.6 years (range, 5.4-6.8 years).

Five patients with bilateral TKA had one of each tibial insert. The diagnosis was osteoarthritis in 95% of cases.

Patients were followed up in clinic by independent trained observers. Patients filled in a questionnaire that included demographic details, Charnley grade, function of their knee using the Western Ontario and MacMaster Universities osteoarthritis score (WOMAC), Knee Society Score (KSS) and Knee Society Function Score, and Short Form 12 (SF 12) questionnaire. At clinical review, weight and height were measured, and body mass index (BMI) was calculated. Active flexion and FFD were measured using a goniometer. Fluoroscopically aligned AP and lateral weight-bearing radiographs of the knees were taken. The KT1000 arthrometer (MEDmetric Corporation, San Diego, Calif) was used according to the manufacturers' protocol. The laxity of the knee was measured at the quadriceps neutral angle of approximately 75° to 80°. The anterior and posterior movements were measured when a 20-lb push and a 20-lb pull were applied. The total laxity was the combined total of anterior and posterior movements. These measurements were repeated with a quadriceps contraction to perform a quadriceps active test. This allowed anterior cruciate ligament (ACL) and PCL movements to be calculated. Anterior and posterior measurements were also made at 30° of flexion with a 30-lb pull and a 20-lb push, and combined for total laxity at 30° flexion.

Medial lateral stability was recorded by measuring the angular displacement from maximal varus to maximal valgus of the knee in extension.

The posterior slope of the tibial component was measured from the lateral radiograph.

Statistical analysis was performed using Stata version 8.1 (StataCorp L.P., College Station, TX). Regression analysis clustered to patient with robust SEs was performed to allow for lack of independence arising from bilateral procedures. Correlation coefficients with 2-tailed significance *P* values were used to calculate any relationship between laxity and outcome measures. Analysis of variance and post hoc Duncan tests were used to compare groups of differing laxity.

Results

There was no significant difference between groups for age at operation, sex, or BMI. There was significantly longer follow-up in group 1 and

Table 1. Details of Groups 1 and 2

	Group 1 (flat)	Group 2 (AP lipped)	*P*
No. of knees (patients)	51 (44)	46 (44)	
Male knees (patients)	31 (25)	26 (25)	
Female knees (patients)	20 (19)	20 (19)	
Average age at operation (SD)	71.1 (6.4)	69.1 (6.1)	NS
Average duration of follow-up (SD) (y)	8.0 (1.0)	6.1 (0.6)	.0001
Average age at follow up (SD)	79.1 (6.4)	75.2 (6.2)	.0001
Average BMI (SD)	29 (4.9)	30.1 (5.8)	NS
Charnley grade			
A	20	18	NS
B	15	23	
C	16	5	
Posterior tibial slope (SD)	0° (2.8)	0° (3.1)	NS

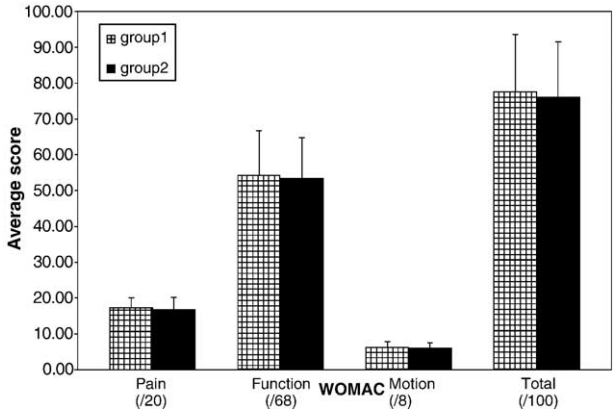

Fig. 2. Mean WOMAC scores for groups 1 (flat insert) and 2 (AP-lipped insert).

hence age at follow-up, as expected in a sequential series. There were more patients who were Charnley grade C in group 1 and more Charnley grade B patients in group 2, but there was no significant difference (see Table 1).

Functional Outcome Scores

No significant differences were seen between the 2 different tibial insert groups for WOMAC score (total, pain, motion, or function components), KSS, Knee Society Function Score, and SF 12 physical and mental scores (Figs. 2 and 3, Table 2).

Range of Motion

There was no difference in active flexion between the groups. Group 1 had an average of 105° ± 13° and group 2 averaged 106° ± 12°.

There was a significant difference in FFD with group 1 averaging 4° and group 2 averaging 2°.

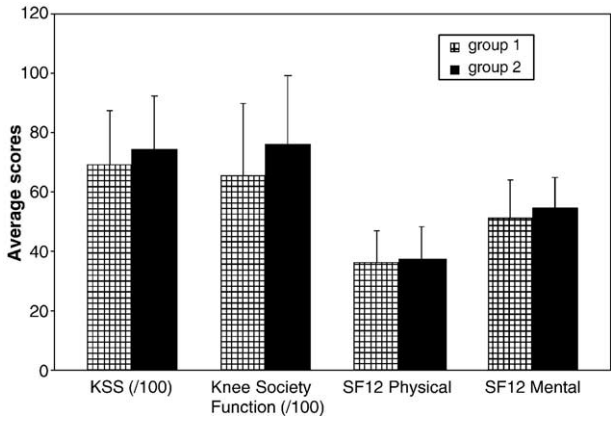

Fig. 3. Mean KSS, Knee Society Function Scores, and SF 12 physical and mental scores for groups 1 (flat) and 2 (AP lipped).

Table 2. Mean Outcome Scores and ROM Results (Regression Analysis Clustered to Patient)

	Group 1 (flat)	Group 2 (AP lipped)	*P*
WOMAC total (SD)	77.5 (16)	76 (15.4)	NS
KSS (SD)	71 (16.6)	74 (17.9)	NS
Knee Society Function Score (SD)	68 (23.9)	76 (23.3)	NS
SF 12 physical (SD)	37.8 (10.3)	37.4 (10.9)	NS
SF 12 mental (SD)	54.5 (11.3)	54.5 (10.3)	NS
Active flexion (SD)	105 (13)	106 (12)	NS
Flexion deformity (SD)	4° (4.3)	2.1° (2.9)	.016
No. of knees with FFD >5° (%)	16 (31)	10 (22)	
Medial-lateral stability (SD)	8.7° (3.3)	8.5° (3.0)	NS

In group 1, 20 knees had no FFD, 8 had 5° or less, 14 had 10° or less, and 2 had 15° and 17°, respectively. In group 2, 28 knees had no FFD, 8 were 5° or less, and 10 were 10° or less.

There was no significant difference in medial-lateral stability between the groups.

Laxity

The results are given in Table 3. A significant difference was seen in the total laxity at 75° and the posterior laxity at 75° with group 2 having greater movement despite the AP-lipped insert. No significant difference was seen between the groups for ACL or PCL movement when a quadriceps active test was performed. There was significantly greater laxity at 30° than 75° for anterior, posterior, and total laxity for both groups. Only 3 knees had total laxity at 75° greater than 10 mm.

The groups were combined and correlations were calculated for functional outcome, ROM,

Table 3. Mean KT1000 Laxity Measurements (Groups 1 and 2 Compared Regression Analysis Clustered to Patient)

	Combined groups	Group 1	Group 2	*P*
Anterior laxity 75° 20-lb pull (mm)	2.8 (1.8)	2.5 (1.8)	3.1 (1.8)	.156
Posterior laxity 75° 20-lb push (mm)	1.7 (1.7)	1.4 (0.8)	2.1 (2.2)	**.026**
ACL movement 75°	0.5 (2.1)	0.4 (2.2)	0.6 (2.0)	.545
PCL movement 75°	4.1 (2.6)	3.6 (2.1)	4.6 (3.0)	.071
Total laxity 75° (mm)	4.6 (3.1)	3.9 (2.3)	5.3 (3.7)	**.037**
Anterior laxity 30° 30-lb pull (mm)	5.8 (3.6)	5.3 (3.3)	6.3 (3.8)	.167
Posterior laxity 30° 20-lb push (mm)	1.5 (0.9)	1.4 (0.6)	1.7 (1.2)	.09
Combined laxity 30°	7.3 (4.0)	6.7 (3.4)	8.0 (4.6)	.104

Values in parentheses are SDs. Bold values indicate a significant difference.

Table 4. Results of Knees Grouped Into Less Than 5 mm, 5 to 10 mm, and More Than 10 mm of AP Laxity at 75°

AP laxity (75°)	0-5 mm	5-10 mm	>10 mm
No. of knees	60	32	3
KSS	70.4 (18.5)	**77.0** (13.4)	**55.3** (19.5)
Knee Society Function Score	70.4 (18.5)	75.3 (23)	68.3 (20.2)
WOMAC	76.6 (16.7)	77.7 (14)	70.0 (18.7)
Flexion	103° (12)	**112**° (10)	**99**° (17)
FFD	4° (4)	2° (3.2)	2° (3.8)

Values in parentheses are SDs. Bold values indicate a significant difference.

demographics, and laxity measurements. There was no correlation seen between anterior, posterior, or total laxity at either 30° or 75° and WOMAC (pain, motion, or function), International KSS, SF 12 (mental or physical), active flexion, FFD, or medial-lateral stability. Correlations with a 2-tailed *P* value of less than .05 were seen for anterior laxity at 75° and maximum flexion ($P = .018$), posterior laxity at 75° and BMI ($P = .008$), and ACL movement at 75° and tibial slope. However, it is likely that these findings are due to chance.

The knees were grouped into those with less than 5 mm, 5 to 10 mm, and greater than 10 mm of AP laxity at 75° (Table 4). Knees with 5 to 10 mm of total AP laxity at 75° had significantly greater ROM than those with more than 10 mm laxity (112° vs 99°, $P = .001$) and a higher KSS (77 vs 55, $P = .05$). The difference in active flexion between knees with less than 5 mm (103°) and knees with 5 to 10 mm of laxity (112°) did not reach significance. There was a higher mean KSS and Knee Society Function Score, and a smaller FFD in the knees with 5 to 10 mm of laxity compared with knees with less than 5 mm, but these also did not reach significance.

Discussion

A number of studies have attempted to relate the laxity of a knee arthroplasty to functional outcome or ROM [1,3,6-9]. One of the problems with instrumented laxity testing is defining the neutral position when measuring anterior and posterior displacement. Most studies have therefore quoted total AP laxity or have taken the resting point as neutral. Warren et al [1] using electronic measuring apparatus found a significant correlation between total AP laxity and passive ROM, and an increased risk for a FFD of more than 4° if the total AP laxity was less than 5 mm. Dejour et al [3] compared PCR and posterior stabilised (PS) knees at 3 to 4 years postoperative using clinical examination and radiological laxity on weight-bearing radiographs, and concluded that more than 10 mm of anterior translation had a worse outcome, as shown by Knee Society Function Scores.

Yamakado et al [7] found no correlation between laxity and ROM in 21 PCR knees at 7 years, with an average total AP laxity of 9.7 mm on KT2000 testing at 30° flexion. They concluded that moderate laxity did not affect outcome.

Matsuda and Ishii [8] using the KT2000 found 9 to 10 mm of total AP laxity in well-functioning mobile-bearing knees at 6 months and recommended this amount of laxity. They also looked at fixed-bearing knees and found a mean total AP displacement of 4.8 mm to 5.8 mm at 75° and 30° in cruciate-retaining knees and concluded that 5 to 6 mm was the suitable degree of AP laxity for that implant [9]. There was no correlation between laxity and Hospital for Special Surgery Score or ROM.

The figures we found for anterior, posterior, and total AP laxity were similar to these previous studies with a mean total AP laxity of 4.6 mm (75°) and 7.3 mm (30°). We attempted to measure the anterior and PCL components by asking the patient to perform a quadriceps contraction simulating the quadriceps active test at 75° flexion. This resulted in greater laxity for the PCL (4.1 mm) and correspondingly less anterior movement (0.5 mm). However, we found no correlation between these results and functional outcome. We found significantly greater flexion in knees with 5 to 10 mm total laxity at 75° than those with more than 10 mm laxity and better KSSs. Therefore, based on our observations, we believe that 10 mm should be the upper limit of laxity with this cruciate-retaining implant. This may not necessarily hold for posterior-stabilized designs. Knees with less than 5 mm of laxity had less flexion but were not statistically worse than the 5 to 10 mm group.

Matsuda et al [6] considered knees with greater total AP laxity at 75° than 30° as having a nonfunctioning PCL and found worse KSSs in these knees. In our series, only 7 knees had greater laxity at 75° than 30°, and none of these had significantly worse results.

Incapacitating instability, pain, and failure can occur both early and late in PCR knees because of PCL deficiency [4,5]. Waslewski et al [4] described at least 15 mm of posterior drawer in their cases that failed because of PCL deficiency. One knee in our series (AP-lipped insert) had 25 mm of total AP laxity at 75° and 28 mm at 30° with a poor result.

The AP-lipped insert used in group 2 may act as a posterior-stabilized knee because of the conforming

design and anterior lip, and so the PCL may not be so important. Surprisingly, however, group 2 had greater laxity than group 1 for all measures, with posterior laxity and total laxity at 75° reaching significance. This group also had a significantly smaller mean FFD. Possible explanations for these findings are that, in group 2, the patients were younger at follow-up and that surgical technique and rehabilitation protocols may have changed over the period of the study. The increased stability afforded by the AP-lipped design may have encouraged a greater release of the PCL. However, Worland et al [10] found no difference in posterior laxity 4 years after bilateral TKA whether the PCL had been recessed or not at the time of operation. Misra et al [11] in a prospective randomized study with the Press-Fit Condylar (PFC) knee (De Puy Orthopaedics, Warsaw, Ind) found no difference in results whether the PCL was retained or sacrificed, suggesting that its role may not be as important in some PCR knees as thought. Despite the differences in laxity between our 2 groups, there were no significant differences in subjective outcomes or ROM. This may be because the WOMAC and the International Knee Society score (KSS) scores are not discriminatory enough for the end points under consideration.

In this study, we were unable to demonstrate a significant relationship between laxity and outcome in cruciate-retaining TKA. However, we found greater flexion and better KSS scores in knees with 5 to 10 mm of AP laxity at 75°of flexion and recommend that careful attention should be placed on accurate bone cuts and soft tissue balancing during PCR TKA to try to keep the amount of total AP displacement within this range.

Acknowledgments

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The Morscher Press Fit acetabular component

A NINE- TO 13-YEAR REVIEW

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We reviewed the results at nine to 13 years of 125 total hip replacements in 113 patients using the monoblock uncemented Morscher press-fit acetabular component. The mean age at the time of operation was 56.9 years (36 to 74). The mean clinical follow-up was 11 years (9.7 to 13.5) and the mean radiological follow-up was 9.4 years (7.7 to 13.1). Three hips were revised, one immediately for instability, one for excessive wear and one for deep infection.

No revisions were required for aseptic loosening. A total of eight hips (7.0%) had osteolytic lesions greater than 1 cm, in four around the acetabular component (3.5%). One required bone grafting behind a well-fixed implant. The mean wear rate was 0.11 mm/year (0.06 to 0.78) and was significantly higher in components with a steeper abduction angle.

Kaplan-Meier survival curves at 13 years showed survival of 96.8% (95% confidence interval 90.2 to 99.0) for revision for any cause and of 95.7% (95% confidence interval 88.6 to 98.4) for any acetabular re-operation.

Cemented acetabular components in general have been recognised for their longevity and predictable performance.[1-3] Cementless acetabular components may have variable medium and longer term results.[4-6] Despite this, uncemented acetabular components are widely used during primary total hip replacement (THR), accounting for 89% of these procedures in Australia[7] and 80% in New Zealand.[8] Some of the designs have been susceptible to early loosening and failure.[9,10] Metal-backed modular acetabular implants may be prone to this because of poor locking mechanisms for their inserts, increased rates of wear compared with all-polyethylene components, and backside wear at the interface between the polyethylene liner and the metal shell.[11]

The Morscher acetabular component (Sulzer Orthopaedics Ltd, Baar, Switzerland), introduced in 1985, is a non-modular flexible press-fit design.[12,13] The polyethylene is bonded directly to a titanium mesh shell to eliminate the potential for backside wear. There is no option for supplementary screw fixation. Berli et al[14] recently reported the results at 15 years of 280 hips implanted by the original designer quoting a survival of 97.5% for aseptic loosening and of 95.3% overall. However, there has been little independent evidence as to whether these excellent results can be achieved in other centres. We describe our experience with the Morscher acetabular component, which we have used since 1993, and compare our results with those of the designer's series.

Patients and Methods

Between January 1994 and December 1997 five orthopaedic surgeons implanted 125 Morscher acetabular components in 113 patients at either of the two hospitals in our city. The type of femoral component used, the material of the head and the approach were at the surgeon's discretion.

There were 80 THRs (64%) in 71 men and 45 (36%) in 42 women. The mean age at operation was 56.9 years (36 to 74). The Charnley grades[14] by patient were as follows: grade A 84 (74.3%), grade B 24 (21.3%) and grade C five (4.4%). The direct lateral approach was used in 65 hips (52%) and a posterior approach in 60 (48%). Osteoarthritis was the primary diagnosis in 106 hips (84.8%; Table I).

The acetabular component was inserted according to the manufacturer's instructions. The acetabulum was reamed to the stated diameter with the implant oversized by 1.5 mm. The inserter was aligned at an abduction angle of 30° referenced from the inferior bevel of the implant. This was impacted to provide a primary press-fit. In women the median size used was 52 mm (48 to 60) and in men 58 mm (48 to 62). A cemented femoral compo-

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Table I. Pre-operative indications for total hip replacement

Diagnosis	Number of hips
Osteoarthritis	106
Developmental dysplasia	9
Previous slipped upper femoral epiphysis	3
Avascular necrosis	3
Rheumatoid arthritis	2
Paget's disease	1
Post-traumatic arthritis	1

Table II. Details of the femoral components used

Femoral component	Number (%)
Uncemented femoral stems	58 (*46.4*)
CLS*	57 (*45.6*)
Wagner cone*	1 (*0.8*)
Cemented femoral stems	67 (*53.6*)
SLS†	52 (*41.6*)
Exeter‡	11 (*8.8*)
MS-30*	4 (*3.2*)
Stainless-steel head (28 mm)	59 (*47.2*)
Ceramic head (28 mm)	66 (*52.8*)

* Zimmer, Warsaw, Indiana
† Sulzer Medica, Winterthur, Switzerland
‡ Stryker Europe, Montreaux, Switzerland

Table III. Details of the study group

	Hips	Patients
Start	125	113
Died	2	2
Follow-up		
Clinical and radiological	108	97
Clinical only	7	7
Radiological only	3	3
Lost to follow-up	2	2
Revised*	3	3

* one hip revised in patient with bilateral THRs

nent was used in 67 hips (53.6%) and a cementless component in 58 (46.4%). A ceramic head was used in 66 hips (52.8%) and a stainless-steel head in 59 (47.2%). All the heads were 28 mm in diameter (Table II).

The patients were invited for clinical and radiological review or seen as part of routine follow-up. The score of Merle d'Aubigné and Postel[15] as modified by Charnley[16] had been determined pre-operatively. A Harris hip score (HHS),[17] the Merle d'Aubigné and Postel score, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score normalised to 100,[18] the short form (SF)-12 generic health score[19] and the Oxford hip score (OHS)[20] were calculated at review with the results given as the mean and SD. An anteroposterior (AP) pelvic radiograph showing the hip with the proximal femur was obtained unless one had been taken within the previous 12 months. Patients who declined to travel were sent questionnaires by post or interviewed by telephone. Radiographs were obtained at their local facility and sent to our institution for assessment. All the patients were cross-referenced to the National Joint Registry[8] and to our local theatre and audit databases to ensure that no revisions had been registered.

At the time of review two patients had died at eight and nine years after surgery. Both had well functioning hips at the time of death. Three hips in three patients had been revised. Two patients (two hips) were lost to follow-up. Three patients (three hips) could not be contacted, but had radiological follow-up at a mean of 8.4 years (7.7 to 9.1). All hips had been functioning well at the last review. The National Joint Registry had no record of revision for any of these five hips. We obtained clinical and radiological review of 111 hips in 99 patients including the three (three hips) who had been revised. Seven patients were contacted by telephone and questionnaires were completed, but they declined to attend for radiological review (Table III). The mean age at review was 67.9 years (46.8 to 84.6) and the mean clinical follow-up was 11.2 years (9.7 to 13.5). Radiological follow-up was at a mean of 9.4 years (7.7 to 13.1).

Radiological evaluation. Radiological evaluation was performed using the zones described by DeLee and Charnley.[21] The femoral component was assessed for evidence of migration, subsidence and the position of the stem. Radiolucent lines and areas of osteolysis were categorised in the seven zones described by Gruen, McNiece and Amstutz.[22] We defined minor osteolysis as a lucency of less than 1 cm in diameter and major osteolysis as one greater than 1 cm. Heterotopic ossification (HO) was assessed using the classification of Brooker et al.[23]

Wear measurements. The Morscher acetabular component is a flattened hemisphere with a 20° bevel. The thickness of the polyethylene varies throughout the circumference. Therefore the standard techniques for measuring wear as described by Martell and Berdia[24] could not be applied. A standard AP radiograph of the hip was taken and digitised using a digital camera of eight megapixels. The abduction angle and the superior polyethylene thickness were measured (Fig. 1) using E-ruler 1.1 freeware (MyCnKnow.com). The superior polyethylene thickness was calculated by counting the pixels to the edge of the titanium backing. The known head diameter of 28 mm was used as a reference. Wear was calculated as the difference in the superior thickness as seen on the post-operative radiograph compared with that on the latest follow-up radiograph. A total of 58 patients had suitable early and late radiographs to allow accurate measurement of the wear rate to be made. Of these, 20 randomly selected films were re-measured by the same observer on two occasions. The abduction angle was accurate to within 0.33° in all cases with a mean difference of 0.11°. The mean difference in measurement of the thickness of the polyethylene was

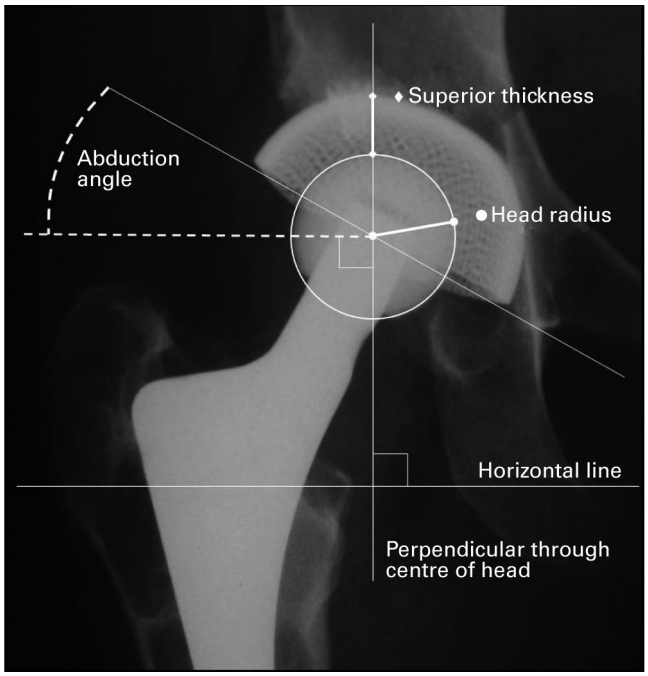

Fig. 1

Anteroposterior radiograph of the hip showing the method used to calculate wear and the abduction angle.

Fig. 2

Anteroposterior radiograph showing excessive polyethylene wear as a result of a high abduction angle requiring revision after seven years.

0.14 mm. The coefficient of repeatability for wear measurements was 0.37 mm.[25] With a mean follow-up of eight years between radiographs this gave an accuracy of 0.05 mm/year for the calculated wear rate.

Statistical analysis. Data were collected and recorded in a custom-made database. Statistical analysis was performed using Microsoft Excel (Microsoft, Redmond, Washington), SPSS (SPSS Inc., Chicago, Illinois) and Simple Interactive Statistical Analysis (SISA, Quantitative skills, Hilversum, Netherlands). An unpaired two-tailed Student *t*-test was used for comparison of normally distributed groups of data, and for continuous data correlation coefficients were calculated with p-values. Statistical significance was set at a p-value of ≤ 0.05. Kaplan-Meier survival curves with the 95% confidence interval (CI) were calculated with the help of a biostatistician.

Results

Three hips were revised. One dislocated in the immediate post-operative period because the acetabular component had been inserted too steeply in a dysplastic acetabulum and required revision at two weeks. A 40-year-old woman with acetabular dysplasia had excessive wear of the polyethylene at seven years which was attributed to a steep abduction angle of 54° (Fig. 2). The hip was revised to a metal-on-metal bearing. A 60-year-old man required revision for deep infection and loosening of the femoral component at 9.3 years.

There were three other re-operations. An unrecognised intraoperative femoral fracture in a 67-year-old man was treated by cerclage wires around an uncemented CLS (Zimmer, Warsaw, Indiana) femoral component. The hip was still functioning well at 13.5 years. A 55-year-old man sustained a traumatic periprosthetic fracture at the tip of a CLS femoral component 11 years after operation. This was treated successfully by a cable plate. The implant was firmly fixed with no sign of osteolysis. One man, aged 64 years at the time of the primary THR, required re-operation at another centre for major pelvic osteolysis at nine years (Fig. 3). The acetabular component was firmly fixed. Therefore allografting was carried out with good results when seen at a follow-up of three years after grafting and 12 years after the original procedure. In addition to the early dislocation that was revised three other hips dislocated giving a dislocation rate of 3.2%. All three stabilised after a closed reduction with no further dislocation.

The Kaplan-Meier survival curves at both ten and 13 years showed survival of 96.8% for revision for any cause (95% CI 90.2 to 99.0) and of 95.7% for any acetabular re-operation (95% CI 88.6 to 98.4) (Fig. 4). No acetabular component required revision for aseptic loosening. If the two hips lost to follow-up had been classified as failures the revision rate would be 4% for any cause at 11 years. However, neither was recorded as having been revised in the New Zealand National Joint Registry which is comprehensive, requires the participation of all surgeons and enjoys 98% compliance.[8]

The Merle d'Aubigné and Postel score improved from a mean pre-operative value of 9.0 (SD 3.2) (pain 2.0, mobility

Fig. 3

Post-operative radiograph at nine years showing major pelvic osteolysis (arrows) in zones I and II which was treated by bone grafting.

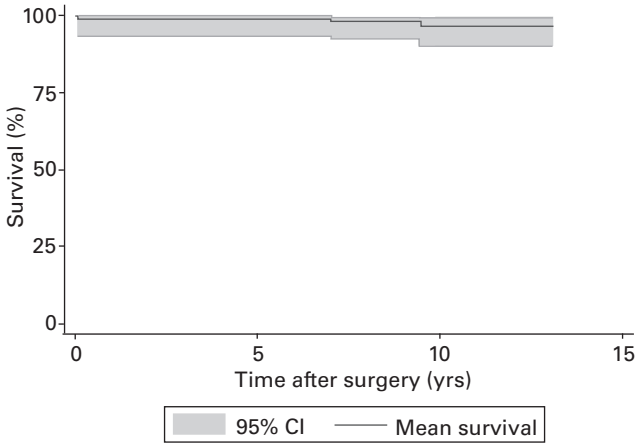

Fig. 4

Kaplan-Meier survival curve with 95% confidence intervals (CI) for revision for any reason.

2.9, function 4.1) to 16.7 (SD 1.7) (pain 5.5, mobility 5.4, function 5.8) (Student *t*-test, $p < 0.001$). At the time of review the mean OHS was 16.1 (SD 4.9), the mean HHS 94.0 (SD 8.5), the mean SF-12 score 75.7 (SD 17.2) and the mean normalised WOMAC score for pain 94 (SD 9.5) and function 90 (SD 11.6).

All the acetabular components appeared to have solid bony ingrowth radiologically. No radiolucent lines were seen and none of the components had migrated. The mean initial abduction angle was 38.0° (22.9° to 60.8°). The mean abduction angle at the time of final review was 37.8° (23.5° to 53.8°). No significant change was seen in inclination (paired Student *t*-test, $p = 0.6$) when comparing early and late post-operative radiographs.

Eight hips (7.0% of the 114 hips with radiological review) had osteolytic defects greater than 1 cm in diameter. One, as mentioned above, had major osteolysis around a well-fixed acetabular component and required bone grafting (Fig. 3). Three others had osteolysis ranging from 1 cm to 3 cm in diameter in zone I of the acetabulum. One further hip had an osteolytic area of less than 1 cm in diameter in zone I giving a rate of any acetabular osteolysis of 4.4% of those hips with radiological review. In four hips major osteolysis was observed around the femoral component. A 60-year-old woman had osteolysis in all zones around a cementless CLS femoral component but was asymptomatic and under regular review. Another patient had osteolysis in Gruen zones 5 and 6 around a cemented MS30 (Zimmer) femoral component but this was also asymptomatic. Two patients had osteolytic defects in zone 7 (1 cm, 1.5 cm × 3 cm as measured on the AP radiograph). Minor osteolysis (less than 1 cm) was seen in zones 1 or 7 in seven hips. Two cemented femoral components (SLS, Sulzer Medica, Winterthur, Switzerland) had subsided 2 mm and 4 mm, respectively, but were asymptomatic.

The overall rate of HO was 33% (38 of 114) (Brooker grade 1, 14, grade 2, 13, and grade 3, 11). All the patients were asymptomatic. There was a statistically significant association between a posterior approach and a higher mean score of HO (mean scores, posterior 0.81, lateral 0.43; $p = 0.04$). There was no association between the use of cemented or uncemented femoral components and the incidence of HO ($p = 0.086$).

The mean linear wear rate was 0.11 mm/year (0.06 to 0.78). The wear rate was significantly higher in patients with a steeper acetabular abduction angle ($r = 0.3$, $p = 0.019$). The one hip revised for excessive wear had an inclination of 54° and a wear rate of 0.78 mm/yr.

There was no statistically significant correlation between the wear rate and the type of material of the head ($p = 0.6$), gender ($p = 0.98$), Charnley grade ($p = 0.45$), approach ($p = 0.99$), the age at the time of operation ($p = 0.36$), the body mass index ($p = 0.52$) or the size of the acetabular component ($p = 0.21$).

No statistically significant correlation was found between the wear rate and osteolysis ($p = 0.93$), or a high abduction angle and osteolysis ($p = 0.8$). However, in the subgroup of seven patients with major osteolysis or reoperation, who had suitable radiographs for accurate measurements there was a mean wear rate of 0.26 mm/year (0.5 to 0.78). By contrast, the group with minor osteolysis or radiolucent lines showed a mean annual wear rate of 0.08 mm/year (0.05 to 0.16) and that with no radiological changes had a mean rate of 0.10 mm/year (0.0 to 0.46).

Discussion

The rationale of the design of the Morscher acetabular component includes the achievement of three-dimensional bony

ingrowth to the titanium mesh, the production of an implant with relatively low stiffness to avoid stress shielding, the avoidance of the complications inherent in a modular system such as dissociation, the achievement of primary press-fit stability without supplementary screw fixation and the avoidance of impingement by the use of the inferior bevel.[12-14] There have been a number of reports from the originator's centre on the acetabular component alone or with a primary focus on the femoral components used with this implant.[12,14,26] However, to our knowledge, there have been no published results on the performance of the Morscher implant from other centres.

In the original series, 280 hips in 261 patients underwent THR using the press-fit component. Only one revision for aseptic loosening was reported giving a survival rate with aseptic loosening as the endpoint of 99.6% at a mean of 6.3 years.[13] Berli et al[14] reviewed the same series of patients ten years later and reported four acetabular revisions (1.4%) at a mean of 9.8 years and 13 (4.6%) at 15 years. The reasons for revision included aseptic loosening in seven, excessive polyethylene wear in three, osteolysis in one, late infection in one and malposition of the component in one. One acetabular component was radiologically loose and another had significant ischial osteolysis, but both were asymptomatic and unrevised. In addition, there were seven isolated femoral revisions giving a total revision rate of 7.1% (20 of 280), at 15 years. No figures were reported for femoral osteolysis. The mean age of the original series was 71 years at operation and 123 of the 261 patients (47%) had died at the time of the 15-year follow-up. By contrast, the mean age of our patients was 56.9 years at the time of surgery with 64% being men. Only two (1.7%) had died at the time of follow-up. Our total revision rate was 2.4% at a mean of 11 years with none undertaken for aseptic loosening.

Berli et al[26] also described a separate series of patients with a mean age of 67 years using the Morscher acetabular component with a matt finish MS30 femoral component. There was survival of 100% of both components at ten years. No acetabular osteolysis was seen, but three acetabular components had radiolucent lines in zone I or zone II. In addition, 6.8% of the femoral components showed osteolysis and 22% had radiolucent lines.

Most cementless acetabular components are modular. The results with first-generation components such as the Harris-Galante acetabular component (Zimmer) have been reasonably good with revision rates ranging from 4% to 6% at 14.9 to 16 years.[4,27,28] However, if all reasons for acetabular revision including dissociation and liner exchanges for wear are considered the re-operation rate increases to between 8.1% and 19%.[4,28] Udomkiat et al[5] reported survival rates at 12 years of 99.1% for failure of fixation of the Anatomic Porous Replacement acetabular component implanted without screws, but this rose to 79% when liner exchange was included. Recently, Utting et al[29] recorded the 12- to 16-year results of the Harris-Galante acetabular component in patients under 50 years of age. There was a survival of 94% for the shell, of 84% for the shell and liner and of 55.3% for impending revision at 16 years.

Osteolysis is often seen after THR and is thought to be initiated by wear particles. The literature records rates of osteolysis from 2.2% to 31% with various metal-backed acetabular components at follow-up of up to 18 years.[4-6,27,28,30-34] Wear between the femoral head and polyethylene liner is inevitable but backside wear between the liner and shell may also occur in modular components. This latter problem is considered to be due to micromovement between the liner and the metal shell, poor conformity between the liner and the shell and the presence of screw holes.[11,35] A non-modular acetabular component has the theoretical advantage of increased thickness of the liner, improved conformity and reduced micromovement, which may reduce wear and osteolysis. Young et al[35] reported less wear and a rate of osteolysis of 2% in non-modular acetabular components compared with 22% in a matched group using a modular device after a mean follow-up of five years. Despite this there are few non-modular cementless acetabular components in current use. A recent report on the titanium coated RM acetabular component at 20 years described survival of 94% with aseptic loosening of the acetabular component as the endpoint and 82.7% for all acetabular revisions.[36] Of the 14 revisions in 93 hips, five were for loosening and seven for osteolysis when the components were found to be well fixed. A further eight hips had acetabular osteolysis, but were not loose or awaiting revision. The authors concluded that the component gave reliable long-term fixation, but that the reduction of wear remained the challenge.[36]

Despite improvement in the locking mechanisms newer designs of uncemented modular acetabular components have still been implicated in occasional liner dissociation, backside wear and osteolysis.[37-40] For the Duraloc 100 acetabular component, osteolysis was found in 41% of the hips at follow-up at seven years, but this may have been related to the use of Hylamer liners.[41]

In our series all the acetabular components appeared to be solidly ingrown with no radiolucent lines, no migration and no revisions for aseptic loosening. Only eight patients had osteolytic defects greater than 1 cm in diameter in either the proximal femur or acetabulum with a rate of 4.6% for any acetabular osteolysis. There have been no isolated femoral revisions.

The mean linear wear rate in our series was 0.11 mm/year which is comparable to those usually reported for stainless steel on cemented conventional ultra-high-molecular-weight polyethylene.[42] The addition of a rigid metal backing to a cemented polyethylene component has previously been shown to increase wear rates by 37% from 0.08 mm/year to 0.11 mm/year.[43] Similar increases in wear have been described for uncemented acetabular components.[44]

Berli et al[14] found polyethylene wear of 0.1 mm/year for a metal-polyethylene articulation and 0.05 mm/year for a ceramic-polyethylene articulation in Morscher acetabular

components with 32 mm heads. We found no difference in the wear rate between ceramic or metal in our series using a 28 mm head, but polyethylene wear in our study was significantly higher in patients with a steeper abduction angle of the component. Berli et al[14] also noted increased wear rates when the abduction angle was greater than 45° although quantitative results were not provided. The survival of the Morscher acetabular component in this series of young and predominantly male patients, was excellent and similar to those of the designer's series.[14]

The revision rate for the Morscher acetabular component in both our series and those from the designer's centre is lower than that of both first- and second-generation modular components at a comparable follow-up if exchange of the liner is included.[14]

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Primary Arthroplasty

The Morscher Press-Fit Acetabular Component: An Independent Long-Term Review at 18-22 Years

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ABSTRACT

Background: There are relatively few 20-year results of uncemented acetabular components, and most of these are modular designs. This study reports the 20-year results of a monoblock press-fit acetabular component.

Methods: A total of 122 total hip arthroplasties (111 patients) using the Morscher cup were reviewed at a mean of 19.7 years. The average age at implantation was 57.3 years (range, 36-74 years), and 81 (66%) were men.

Results: Twenty-two patients (25 hips) had died. Seven hips were revised, including 5 acetabular revisions. Six patients (6 hips) declined to participate but were known not to have been revised. The mean Oxford hip score was 41.1 (range, 22-48), and the mean reduced Western Ontario and McMaster Universities Osteoarthritis Index score was 5.7/48 (range, 0-24). Eccentric wear was seen in 13 (15.7%) and major osteolysis in 14 (17%) of 82 surviving hips with radiographs. The all-cause revision rate was 0.32 per 100 observed component years (95% confidence interval [CI], 0.13-0.66). The 20-year Kaplan-Meier survival was 93.4% (CI, 86.6-96.8) for all-cause revisions, 95.5% (CI, 89.4-98.1) for any acetabular revision, and 97.1% (CI, 91.2-99.1) for acetabular aseptic loosening, wear, or osteolysis.

Conclusion: The Morscher acetabular component has continued to perform well at 20 years despite using conventional polyethylene with results that match or surpass other cementless acetabulae.

Uncemented acetabular components are increasingly being used in primary total hip arthroplasty, now accounting for 95% of hips in Australia [1], 87% in New Zealand [2], and 63% in the United Kingdom [3]. Despite their common use, it is still not clear whether cementless cups confer a long-term advantage over cemented cups [4,5], with relatively little published evidence on the longevity of uncemented acetabular components at 20 years (Table 1). The majority of uncemented components are modular, with many starting to fail after 10 years due to poor locking mechanisms, wear, and osteolysis [15–17]. Monoblock uncemented components may offer an advantage by eliminating the problems of liner dissociation and reducing backside wear. Excellent long-term survivorship has been reported [8,18], and they may be a cheaper alternative to modular systems [19,20].

The Morscher cup (Sulzer Orthopedics Ltd, Baar, Switzerland), introduced in 1985, is a monoblock, cementless, flexible press-fit cup [21,22]. The only long-term results are those of the designer series with a 95.3% overall survival at 15 years [23]. We have previously reported our independent results of the Morscher cup at 9-13 years [24]. The purpose of this study is to provide an independent, long-term, concise follow-up of the same cohort at 18-22 years.

Patients and Methods

Between January 1994 and December 1997, 122 Morscher acetabular components were implanted in 111 patients at either of

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Table 1
Series Reporting 20-y Results of Uncemented Acetabular Components.

Author	Acetabular Implant	Number of Hips (Living)	Mean Follow-Up, y	All-Cause Revisions, n (%)	All Cup Revisions, n (%)	Survivorship	
						All-Cause Revisions (%)	Cup Revision
Kim, 2005 [6]	PCA	131 (110)	19.4	33 (25)	23 (18)	Not stated	79% all cause
Belmont et al, 2008 [7]	Tri-Spike (DePuy)	223 (119)	22.0	50 (22)	47 (21)	74	93.6% aseptic loosening; 85.8% all cause
Ihle et al, 2008 [8]	RM Classic	93 (67)	19.8	17 (18)	14 (15)	79.7	94.4% aseptic loosening; 82.7% all cause
Della Valle et al, 2009 [9]	PCA	204 (124)	20-22	74 (36)	62 (30)	Not stated	86% aseptic loosening, wear, osteolysis
Howard et al, 2011 [10]	Various	9584	3.2-15	Not reported	1124 (11.7)	Not reported	20-y survivorship: 72.8% shell, 59.3% shell and liner
Saito et al, 2011 [11]	HG1	76 (38)	22.5	4 (5.3)	3 (3.9)	86.8	92.1% all cause
Loughead et al, 2012 [12]	PCA	311 (140)	23	47 (15)	35 (11)	83	88% all cause
Stefl et al, 2012 [13]	HG1	120 (42)	23	22 (18)	22 (18)	76	92% mechanical failure (wear, loosening, osteolysis); 97% aseptic loosening
Kim, 2015 [14]	DURALOC (DePuy)	342	26	Not reported	74 (22)	Not stated	78%-79% all cause
This study	Morscher	122 (97)	19.7	7 (5.7)	5 (4.1)	93.4	95.5% all cause; 97.1% aseptic loosening, wear, osteolysis

HG1, Harris Galante 1; PCA, Porous-Coated Anatomic.

the 2 hospitals in our city. The Morscher cup is a flattened hemisphere with an inferior bevel and has 4 layers of titanium mesh bonded to the back of the conventional ultra-high-molecular-weight polyethylene to eliminate the potential for backside wear. There is no option for supplementary screw fixation (Fig. 1).

The cup was typically chosen for younger, more active patients. The type of femoral component used, the material of the head, and the approach were at the surgeon's discretion.

Patients were invited for clinical and radiologic review. Both Oxford hip score (OHS) and a reduced Western Ontario and McMaster Universities Osteoarthritis Index score (RWS) were collected [25,26]. The RWS is a shortened version of the Western Ontario and McMaster Universities Osteoarthritis Index score and includes 5 pain and 7 function questions scored 0-4, where 0 is best to give a score 0-48 [27]. Questionnaires were mailed out if the patient declined to attend with telephone follow-up as required.

Radiologic evaluation was assessed for osteolysis using the zones described by DeLee and Charnley [28] and Gruen et al [29]. Minor osteolysis was defined as a lucency of <1 cm in diameter and major osteolysis as one >1 cm on either anteroposterior or lateral view as in our previous article [24].

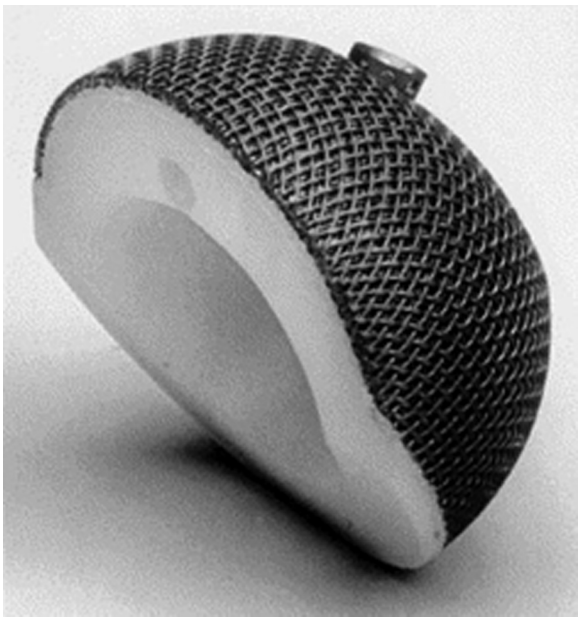

Fig. 1. The Morscher press-fit cup.

Ethics committee approval for this study was given by the University of Otago Ethics Committee (Health). The study was supported by a grant from the Wishbone Trust, New Zealand.

Statistical Analysis

The *sts* command in Stata, version 14.1 (StataCorp LP, College Station, TX), was used to perform the Kaplan-Meier analyses to estimate the survival functions with patients censored at time of death or revision.

Results

A total of 122 Morscher acetabular components were implanted in 111 patients by 5 different surgeons. The predominant underlying pathology was osteoarthritis. The mean age was 57.3 years (36-74 years), and 80 (64%) hips were in men. A cemented stem was used in 63 hips (52%), most commonly the monoblock SLS (Protek AG, Bern, Switzerland) and an uncemented stem used in 59 (48%), mainly the CLS Spotorno stem (Protek AG, Bern, Switzerland). A 28-mm head was used in all cases, with 57 hips (47%) having a stainless steel head and 65 hips (53%) having a ceramic head (Table 2). Cup sizes ranged in women from 48 to 60 mm, with a median of 52 mm and in men from 48 to 62 mm with a median of 58 mm.

At the time of this review, at a mean of 19.7 years from the date of operation, 22 patients (25 hips) had died (20%). The mean time to death from operation was 13.8 years (6.8-19.8 years) with a radiologic follow-up mean of 12.6 years. None of these patients had undergone a revision procedure. Two hips had osteolytic lesions >1 cm on their last radiograph. Seven hips (7 patients) have been revised at an average of 11.9 years (0.1-17.4 years).

There were 90 surviving hips in 82 patients (Fig. 2). Of these, there was a radiologic review on 82 hips (91%), and patients completed outcome scores for 64 hips (71%). Two patients who responded to questionnaires declined to undergo an X-ray. Six surviving patients (6 hips; 4.9%) declined to participate. All lived locally and had no record of any further surgery. Three of these patients had radiologic follow-up to a mean of 9.2 years (7.3-12.8 years), one of whom was known to still have a functioning hip at 17 years. Three others without X-rays were known to have well-functioning hips at 11, 12, and 18 years. None of these patients had a revision of their hip arthroplasty registered on our national joint registry. Two patients (3 hips) thought to be lost to follow-up from the original series were found to be duplicates of other patients due to data entry errors.

Table 2
Details of Patients, Operative Approach, and Femoral Components Used.

Age, mean (range), y	57.3 (36-74)
Gender, n (%)	
Men (80 hips)	71 (64%)
Women (42 hips)	40 (36%)
Approach (hips), n (%)	
Lateral	63 (52%)
Posterior	59 (48%)
Charnley grade (patient), n (%)	
A	83 (75%)
B	23 (21%)
C	5 (4%)
Cemented stem (head material), n (%)	
SLS (SS)	49 (40.2%)
Exeter (SS)	8 (6.6%)
Exeter (ceramic)	2 (1.6%)
MS-30 (ceramic)	4 (3.3%)
Uncemented stems (head material), n (%)	
CLS (ceramic)	58 (47.5%)
Wagner Cone (ceramic)	1 (0.8%)

SS, stainless steel head; MS-30, Morscher-Spotorno (Zimmer-Biomet, Warsaw, IN); SLS, self locking straight; CLS, CLS Spotorno.

Revisions and Reoperations

In our original report, there had been 3 revisions: one cup was revised at 2 weeks after malposition in a dysplastic acetabulum leading to dislocation, a cup implanted at an abduction angle of 54° was revised at 7 years for polyethylene wear in a 40-year-old woman with acetabular dysplasia, and a 60-year-old man required revision for deep infection at 9.3 years at which time the acetabular cup was found to be firmly fixed.

Since then, further 4 hips have been revised giving a total of 7 hips (7 patients) revised of the 122 hips (5.7%) with 5 acetabular revisions (4.1%). Two patients had isolated acetabular revision for osteolysis at 15.3 and 17.4 years, respectively. There were only 2 femoral revisions: one was due to an open periprosthetic femoral fracture sustained in a mining accident at 16.7 years and the other was for aseptic loosening of a cemented femoral component at 17 years. In both cases the cup was well-fixed at the time of revision surgery.

In addition, 2 patients underwent open reduction and internal fixation of periprosthetic femur fractures (at 0.1 and 11 years). One remained unrevised at the time of death at 17.1-year follow-up and the other declined to participate but was known to be functioning and unrevised at 17 years. Another patient underwent bone grafting of a major osteolytic defect behind a well-fixed acetabulum at 10 years with the acetabular component left in situ. This hip remains unrevised at 20 years but shows recurrent osteolysis around both the cup and the stem.

Survivorship

The all-cause revision rate was 0.32 per 100 observed component years (ocy; 95% confidence interval [CI], 0.13-0.66). The Kaplan-Meier curves at 20 years are shown in Figure 3. They

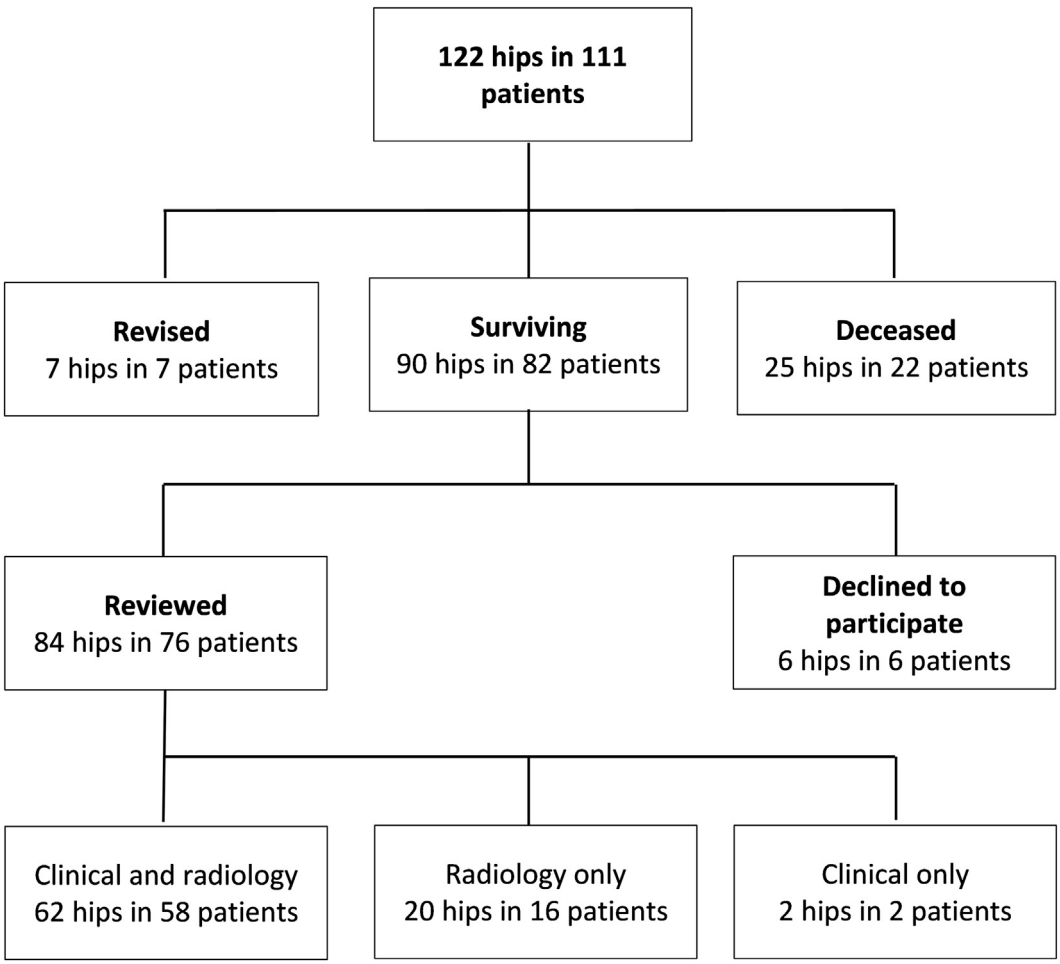

Fig. 2. Status of patients at final review.

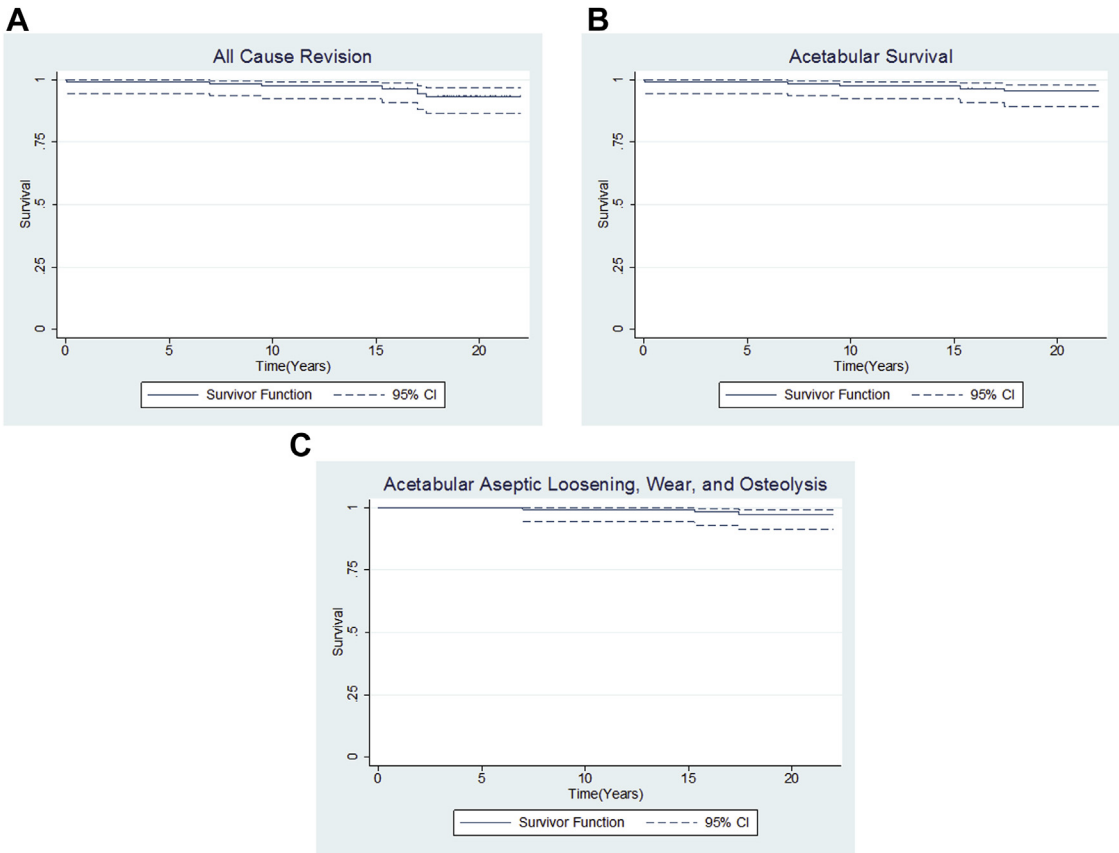

Fig. 3. (A) Kaplan-Meier survival curve for all-cause revision, (B) Kaplan-Meier survival curve for acetabular revision, and (C) Kaplan-Meier survival curve for acetabular wear, loosening, and osteolysis. CI, confidence interval.

demonstrate 93.4% survival at 20 years for any all-cause revision (CI, 86.6-96.8) and 95.5% survival (CI, 89.4-98.1) for acetabular revision for any cause. The acetabular survival for aseptic loosening, wear, or osteolysis was 97.1% (CI, 91.2-99.1).

Clinical and Radiologic Outcomes

Patient reported scores were available for 64 of 90 (71.1%) surviving unrevised hips at mean follow-up of 18.4 years (17.1-20.7 years). The mean OHS was 41.1 (range, 22-48), with 85% good to excellent scores. The mean RWS was 5.7/48 (11.9%; range, 0-24).

Radiology was available for 108 of 122 hips (89%), including those revised or deceased with mean radiologic follow-up of 17.1 years (9.8-20.7 years). The distribution of osteolytic lesions for the whole series is shown in Figure 4.

Of the 82 surviving hips with a radiologic review, no acetabular components showed any radiologic evidence of loosening. Major osteolysis was seen in 14 (17%) and eccentric wear in 13 (15.7%). None of these hips are symptomatic, and no revisions are planned. There was a major lysis behind the acetabular component in 7 hips (8.5%), of which 3 cups showed eccentric wear. In addition, there was a minor lysis behind the acetabular component in 10 hips (12%), mainly in zones I and II. On the femoral side, major osteolysis was seen in 8 hips (9.8%) and minor lysis around the femoral component in 16 hips (20%).

Of the 8 hips that showed major osteolysis in the original series, 2 have died and 2 hips have been revised. One, as mentioned previously, was bone grafted and remains unrevised. Of the remaining 3 hips, 1 has shown significant progression but has not required revision and 2 remain essentially unchanged. There appeared to be no relationship between head material, femoral fixation, and osteolysis or wear.

Discussion

The Morscher cup in this series has continued to function well at 20-year follow-up with results that match or surpass other uncemented components, whether modular or monoblock. Despite the popularity of cementless cups, there are few 20-year results published, and these are mainly for modular first-generation designs such as the Harris-Galante (HG1; Zimmer, Warsaw, IN) and the Porous-Coated Anatomic (Howmedica, Rutherford, NJ) [6,7,9–14] (Table 1). Although results of 86%-96% have been reported for acetabular shell survival, if liner exchanges, impending revisions, and other reoperations are included, the survival drops to 55%-74% [7,9,10,13,30,31].

More modern designs may have improved results. McLaughlin and Lee [32] reported 98% acetabular survival at 16 years with a threaded hemispheric titanium shell and Rozkydal et al [33] reported 86.6% radiologic survivorship of the CLS expansion cup at 16 years. However, Hallan et al [16] from the Norwegian registry reported that none of the modular cups in their study had satisfactory long-term results due to high rates of wear, osteolysis, aseptic loosening, and dislocation. Howard et al [10] also noted an increased risk of revisions in the second decade for these reasons and found no evidence that more recently introduced designs performed better than the HG1 cup.

The Morscher cup was designed and introduced in 1985. Berli et al [23] reported 95.5% survival at 15 years for revision of any cause in the designer series of 280 hips. There were 13 acetabular

Fig. 4. Distribution of osteolytic lesions seen for the 108 hips with radiologic review including hips before revision (major >1 cm diameter, minor <1 cm diameter).

revisions (4.6%) and 7 femoral revisions giving a total revision rate of 20 of 280 (7.1%) at 15 years. The average age of the original cohort was 71 years at operation, and 123 of the 261 patients (47%) had died at the time of the 15-year follow-up.

Garavaglia et al [34] reported on a large series of 561 hips using the Morscher cup at 10 years. The mean age was 69.3 years, and 55% were women. There was 98.8% cup survival with no revisions for acetabular loosening. They reported no acetabular osteolysis but 8.3% stem osteolysis. However, they had only 59.7% follow-up.

In contrast to these series, the average age of our patients was 57.3 years at the time of surgery, with 66% being men. At 20 years, there was 93.4% survival for revision for any cause, 95.5% survival for acetabular revision for any cause, and 97.1% survival for acetabular aseptic loosening, wear, or osteolysis. Other surgeons may have revised the cup that was bone grafted at 10 years for osteolysis and the femoral revision for osteolysis could be secondary to wear debris. If we include these cases, the survival for any wear-related reoperation of acetabulum or femur is still 95.2% (CI, 88.8-98.0) at 20 years.

These results compare favorably with the designer's series at a longer term follow-up. Technical errors contributed to the immediate revision at 2 weeks for dislocation and to the cup revised at 7 years for excessive polyethylene wear due to a steep abduction angle. The inferior bevel of the Morscher cup makes it more demanding to insert with the correct abduction angle.

The revision rate in this series of 0.32 per 100 ocy is lower than that for the Morscher cup in our national joint registry of 0.49/100 ocy in combination with the CLS stem and 0.42 to 0.65/100 ocy with cemented stems (Exeter and MS-30) [2]. It compares favorably with the average revision rate in our registry of 0.73/100 ocy [2].

The rate of acetabular osteolysis (major 8.5%, minor 12%) and eccentric wear (16%) of surviving hips in our series is concerning and has progressed from our earlier study. We attribute this to the use of conventional polyethylene. The lowest reported rates of acetabular osteolysis at 20 years are 8%-13% [8,13]. However, rates of 30%-54% are more typical with modular cups [6,7,9,14].

Like Garavaglia et al [34], we have seen no cases of acetabular loosening either at revision or radiologically, whereas Berli et al [23] reported only 2.9% acetabular loosening. The same mesh is used in the modular Fitmore cup (Zimmer Inc, Warsaw, IN), which has 100% survival for aseptic acetabular loosening and 94% survival for all-cause revision at 12 years [35].

The long-term patient-reported scores are surprisingly good and may reflect the relatively young age at time of operation. The average OHS of 41.1 and 85% with good or excellent results compares well with our joint registry 10-year average of 41.9 with 87% good and excellent scores [2].

Other monoblock cups have promising long-term results. The RM cup (Mathys Ltd Bettlach, Bettlach, Switzerland), like the Morscher, is a relatively flexible cup but has a coating of pure titanium particles instead of the 4-layer titanium mesh [8,19]. Ihle et al [8] reported 94.4% survival of the RM cup at 20 years for aseptic loosening and 82.7% for all acetabular revisions. Biemond et al [36] reported on 100 hips aged <50 years using the CLS stem with the RM cup at 18.4 years. There were 15 revisions giving approximately 80% survival for all-cause revision at 19 years.

Other monoblock designs have used polyethylene compression molded into a shell, which may result in a stiffer cup [18,37]. Poultsides et al [37] reported no revisions for osteolysis or loosening at 10-15 years using a cup with a titanium backing. Recently, De Martino et al [18] reported 100% cup survival for aseptic loosening and 96.3% survival for all-cause revision at 15 years in a series of 63 hips using a tantalum monoblock cup.

Despite these results, systematic reviews have not shown any advantage of a monoblock over a modular cup concluding that the purported advantages are not substantiated by lower wear rates, frequency of cup failure, or acetabular osteolysis [38] and that both third-generation modular cups and monoblock cups had consistently good results [39].

Strengths of this study are the low loss to follow-up and the low death rate in the cohort at 20 years due to their relatively young age at operation. It is a consecutive series of the first 122 hips using the Morscher cup, so, it includes the learning curve. Several surgeons were involved, and there were no exclusions. A weakness is that it is a retrospective review and a variety of femoral components were used. Although there is no complete radiologic and clinical follow-up, we are confident that there have been no revisions in those patients who declined to participate.

The Morscher cup, in our series, has results that match or surpass other uncemented cups at 20-year follow-up. There have been no cases of acetabular loosening. We attribute the concerning osteolysis rates to the use of conventional polyethylene. The combination of the monoblock design to eliminate backside wear, the flexibility of the cup, which may reduce polyethylene wear, and titanium mesh for fixation appears to be factors in its success. The Morscher cup is no longer available; however, long-term results such as these can be used to guide future implant design. A similar design with a modern highly cross-linked polyethylene would be a logical development.

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Hybrid Fixation for Total Hip Arthroplasty Showed Improved Survival Over Cemented and Uncemented Fixation: A Single-Center Survival Analysis of 2156 Hips at 12-18 Years

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ABSTRACT

Background: Despite increased use of uncemented and hybrid fixation, there is little evidence of their superiority over cemented implants. The aim of this study is to compare the long-term survivorship of cemented, hybrid and uncemented total hip arthroplasty (THA) at varying ages.
Methods: A total of 2156 hips (1315 cemented, 324 uncemented, and 517 hybrid) were performed in a single center between 1999 and 2005 with follow-up through to 2017. Registry and local databases were used to determine revision rates and cause. Unadjusted and adjusted competing risk survival analysis was performed.
Results: The cumulative incidence of all-cause revision at 18 years was cemented 10.9%, uncemented 8.9%, and hybrid 6.5%. Cemented fixation had a statistically significant higher risk of all-cause revision than hybrid in the adjusted model for all ages to 65 years (subhazard ratios [SHRs], 2.28-4.67) and a higher risk of revision for loosening, wear, or osteolysis at all ages (SHRs, 3.25-6.07). Uncemented fixation showed no advantage over hybrid fixation at any age, but did show advantages over cemented at younger ages (≤60 years) for all-cause revision (SHRs, 2.3-4.3).
Conclusion: Hybrid fixation with conventional polyethylene shows an advantage over cemented hips at all ages. Uncemented THA showed improved survival over cemented only at younger ages and no advantage over hybrid THA.

Total hip joint arthroplasty (THA) is a highly successful procedure with impressive long-term survival and low revision rates. The average age of patients undergoing THA is 68-70 years so many patients will die with unrevised components. However, increasing life expectancy and the demand for surgery in younger patients mean that an implant must often last through the second and even third decades. Age is known to be a determinant of outcome with younger patients having higher revision rates. The debate on the best mode of fixation continues. Cemented stems have excellent long-term results, but cemented cups have been less successful although some of the implants used are now considered obsolete [1–5]. First-generation, uncemented, acetabular components had problems especially with locking mechanisms and accelerated polyethylene wear after 10 years [6,7]. However, newer designs with the use of highly cross-linked polyethylene liners have resulted in low wear, significantly improved rates of osteolysis, and improved survival rates [8–10,11]. There has also been increased use of monoblock flexible uncemented cups with excellent long-term results [12,13].

In New Zealand and elsewhere, there has been a shift away from cemented THA over the last 20 years to uncemented or hybrid components [8–10]. However, despite their increased use, there is little evidence to show their superiority over cemented THA [8–10,14]. This has been termed the uncemented paradox [15].

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Uncemented components may have an increased rate of early revision most commonly due to dislocation, infection, or fracture. However, the anticipated improvement in survival curves at longer follow-up has yet to be seen [8–10]. Some registry data suggest that uncemented or hybrid fixation may have improved survivorship in younger patients while cemented fixation has better results in older patients [8–10].

There is increasing pressure from funders to limit choice of implant and mode of fixation. This is not new; cost constraints and a desire to follow evidence-based practice led to the development of a cement-only policy between 1999 and 2004 in our public hospital with exceptions only allowed after discussion at a departmental meeting. There was unrestricted choice at our private hospital. As a consequence of this, we have observed that the commonest revision we see is for aseptic loosening of cemented acetabulae in the second decade after THA, while it has been very unusual to revise uncemented or hybrid hips despite their use in younger, more active patients.

Our hypothesis therefore is that all cemented THA has higher revision rates due to acetabular loosening than hybrid and uncemented THA at long-term follow-up. The primary aim of this study is to investigate long-term survival of cemented, uncemented, and hybrid THA with the end points of all-cause revision for and revision for loosening, wear, and osteolysis. The secondary aim is to determine whether this varies with age.

Methods

Setting and Patients

Our public hospital services around 200,000 patients spread over a large geographic area with one major city of 140,000 and a large rural farming population. There is also a private hospital with the majority of surgeons operating at both hospitals. Over the study period, there were 8 surgeons performing THA using a variety of implant systems. All had extensive experience of both cemented and uncemented systems which were introduced to our hospital during the 1990s.

All patients who had undergone THA between July 1999 and December 2004 at either of our hospitals were identified from the New Zealand National Joint Registry (NZJR) which has 98% compliance [8]. Data collected included details of diagnosis, implants used, date of death, surgeon grade, and date and reason for revision. Our departmental database was used to search for any revision procedure including excision arthroplasty and cross-referenced to the NZJR records. All reasons for revision were checked through use of electronic patient chart and radiological records and the primary reason for revision noted. We excluded THA for acute hip fracture but included all other indications for surgery.

The demographic details are detailed in Table 1. The commonest reason for THA was osteoarthritis (89%). The mean age of patients undergoing uncemented and hybrid hips was younger than that for cemented THA. A lateral approach was used in 1357 (63%) hips and a posterior approach in 797 (37%). Two hips underwent a trochanteric osteotomy and were included in the lateral group for statistical analysis.

The most frequently used cemented combinations were Exeter/Contemporary (Stryker, Kalamazoo, MI) and Muller straight stem (SLS)/Muller low profile Polyethylene cup (Zimmer, Winterthur, Switzerland). The CLS Spotorno (Zimmer) was the most frequently used uncemented stem. A variety of uncemented cups were used including the Morscher Press Fit (Sulzer Orthopaedics, Baar, Switzerland), Fitmore (Zimmer), CLS Expansion cup (Zimmer), Reflection (Smith and Nephew, Memphis, TN), RM Pressfit (Mathys Ltd Bettlach, Switzerland), and Trident (Stryker).

Surgical Technique

Spinal anesthesia was used routinely. Perioperative antibiotics (cefazolin) were given on induction and for 24 hours. Thromboprophylaxis was at surgeon discretion but was either aspirin or low-molecular-weight heparin for standard-risk patients and warfarin for patients at high risk of deep vein thrombosis or pulmonary embolism. Tranexamic acid was not used routinely during this period.

For cemented cups, the acetabulum was reamed using sequential hemispherical power reamers. Cysts were de-roofed and a combination of pits and multiple drill holes made with the aim of producing a porous bed of bone for cementation. Medial wall bone graft was used as required. Hydrogen peroxide–soaked gauze was used to dry the acetabulum after pulsed lavage. Cement was pressurized using a commercially available pressurizer. Polymethylmethacrylate beads were present on the Reflection All Poly cup (Smith and Nephew) and Contemporary cups (Stryker). All polyethylene was standard (not highly cross-linked) for the cemented cups.

Cemented stems were inserted using third-generation techniques. After preparation of the canal with broaches, a cement restrictor was inserted. The canal was cleaned with pulsed lavage and a brush and packed with hydrogen peroxide or saline-soaked gauze. The cement was vacuum mixed and inserted with a retrograde technique using a cement gun and a proximal pressurizer.

Insertion of uncemented cups was according to manufacturer's instructions. A press fit was obtained usually by under-reaming by 1-2 mm. Supplementary screws were used if required. Uncemented stems were inserted after appropriate preparation with implant-specific broaches.

Table 1
Demographic Details of All Patients.

Details of Procedures and Patients	All Procedures	Uncemented	Hybrid	Cemented
	Total			
Number of procedures	2156	324	517	1315
Public, n (%)	1333 (61.8)	112 (34.6)	158 (30.6)	1063 (80.8)
Approach posterior (%)	797 (37.0)	148 (45.7)	176 (34.0)	473 (36.0)
Number of revisions (%)	163 (7.6)	21 (6.5)	26 (5.0)	116 (8.8)
Time to revision (y) for those with a revision event, mean (SD)	8.8 (4.2)	6.2 (4.4)	9.5 (5.0)	9.2 (3.8)
Revision rate/100cys (95% CI)	0.64 (0.55-0.75)	0.51 (0.32-0.78)	0.38 (0.25-0.56)	0.80 (0.66-0.96)
Distinct patients	1888	278	448	1186
Age mean (SD), y	65.6 (11.6)	51.7 (9.2)	60.3 (8.7)	70.8 (9.2)
Sex male, n (%)	890 (47.1)	175 (62.9)	249 (55.6)	478 (40.3)
Deaths, n (%)	712 (37.7)	30 (10.8)	80 (17.9)	609 (51.3)

SD, standard deviation; CI, confidence interval.

Table 2
Details of Reasons for Revision for Each Fixation Group.

Reason for Revision	Uncemented (N = 324)	Hybrid (N = 517)	Cemented (N = 1315)	Total (N = 2156)
Acetabular loosening	2 (0.6%)	3 (0.6%)	60 (4.5%)	65 (3%)
Femoral loosening	3 (0.9%)	9 (1.7%)	12 (0.9%)	24 (1.1%)
Both loose	0	1 (0.2%)	17 (1.3%)	18 (0.8%)
Wear	4 (1.2%)	0	1 (0.07%)	5 (0.2%)
Osteolysis	0	1 (0.2%)	2 (0.14%)	2 (0.1%)
Dislocation	8 (2.5%)	6 (1.2%)	5 (0.4%)	19 (0.9%)
Infection	1 (0.3%)	1 (0.2%)	12 (0.9%)	14 (0.6%)
Fracture	2 (0.6%)	4 (0.8%)	7 (0.5%)	13 (0.6%)
Other	1 (Cup malposition)	1 (Pain)	0	2 (0.1%)
Total	21	26	116	163

The head size was 28 mm in 1996 hips, 22 mm in 143, 32 mm in 14, 36 mm in 2, and 38 mm in 1 hip. The head material was metal (stainless steel or chrome cobalt) in 1708 hips (79%) and ceramic in 448 (21%).

Conventional polyethylene was used for 2147 hips (95.7%), highly cross-linked polyethylene for 93 (4.1%), and ceramic on ceramic and metal on metal for 2 hips each.

Statistical Methods

Statistical analysis was performed using revision for any reason as the primary end point with aseptic loosening, wear, or osteolysis as a secondary end point. A competing risks survival analysis (with death as a competing risk for all analyses and revision for other reasons added as a competing risk for models investigating specific reasons for revision) adjusting for age (as a continuous variable which was allowed to interact with cementing group), gender, public or private hospital, surgical grade (consultant vs trainee), approach (posterior vs other), and bearing surface was undertaken. Nonlinearities in the association with age were investigated, and where appropriate modeled, through the addition of a quadratic term with retention based on the lowest Akaike Information Criterion value. Multiple procedures on the same patient (left and right hips) were accommodated by using robust clustered (by patient) standard errors. Cumulative incidence curves were used to show differences between cementing groups, including at selected ages in the models including age. Analyses were performed using Stata 15.1 with 2-sided $P < .05$ considered statistically significant.

Results

The revision rate/100 observed component years (ocys) was significantly higher for cemented hips (0.80/100ocys) than hybrid hips (0.38/100ocys). The rate for uncemented hips (0.51/100ocys) was not significantly different from either of the other 2 groups (Table 1).

Details of reasons for revision are given in Table 2. The commonest reason for revision was isolated acetabular loosening in cemented THA. In the uncemented group, dislocation was the commonest cause for revision (8/324 hips, 2.5%), which was significantly higher than for cemented hips (5/1315, 0.4%; $P = .001$). Acetabular failure due to loosening, wear, or osteolysis was significantly higher for cemented (80/1315, 6.1%) than hybrid (5/517, 1.0%) and uncemented hips (6/324, 1.9%; $P = .001$).

Survival Analysis

All-Cause Revision and Revision for Loosening, Wear and Osteolysis

The cumulative incidences of all-cause revision at 18 years, allowing for the competing risk of death, were 10.9% (cemented), 8.9% (uncemented), and 6.5% (hybrid) (Fig. 1).

There was a significantly greater risk for cemented compared to hybrid ($P = .011$) but no difference between cemented and uncemented ($P = .390$) or between uncemented and hybrid ($P = .282$).

The corresponding figures for revision for loosening, wear, or osteolysis were 8.8% cemented, 3.8% uncemented, and 3.5% hybrid (Fig. 2). There was a higher risk for cemented compared to both uncemented (subhazard ratios [SHRs], 2.36; 95% CI, 1.11-5.01; $P = .026$) and hybrid (SHRs, 2.57; 95% CI, 1.46-4.53; $P = .001$) but not between the uncemented and hybrid groups ($P = .848$).

Effect of Age

All-Cause Revision

There was an age-cementing interaction with evidence that cemented had higher risk compared to both uncemented and hybrid at age 50 (SHRs, 4.34 and 4.84, respectively, both $P < .001$), age 55 (SHRs, 3.16 and 3.83, both $P < .001$), and age 60 (SHRs, 2.30 and 3.03, both $P \leq .012$). Cemented had higher risk compared with hybrid at age 65 ($P = .001$) and age 70 ($P = .050$), but there was no evidence of differences at age 75 (Table 3).

Adjusting for gender, bearing combinations, hospital, approach, and surgeon level did not alter the pattern of results as shown above although the SHRs were attenuated (Fig. 3, Table 3). Cemented hips had a higher risk of revision compared to hybrid at ages 50 to 65 (all $P \leq .026$) but with no evidence of differences at ages 70 or 75. Cemented hips had a significantly higher risk of revision than uncemented at ages 50 and 55 (both $P \leq .026$). Uncemented fixation had higher SHRs than hybrid at all ages in the fully adjusted model (1.39 to 1.97) and compared with cemented at age 75 (1.4) but none reached statistical significance. None of the other variables in the model were statistically significant.

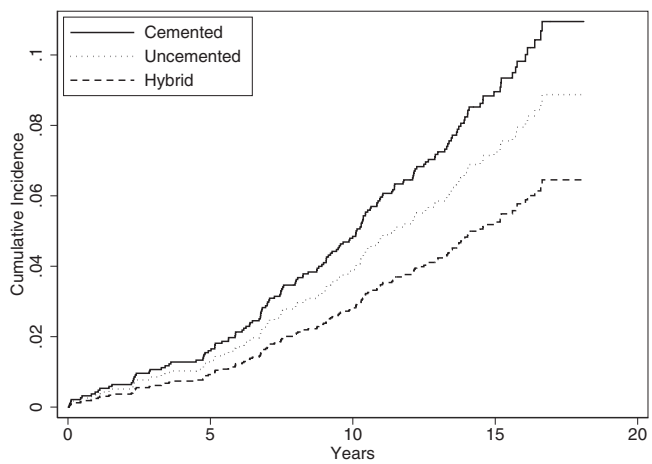

Fig. 1. All-cause revision: unadjusted competing risk regression with death as competing cause.

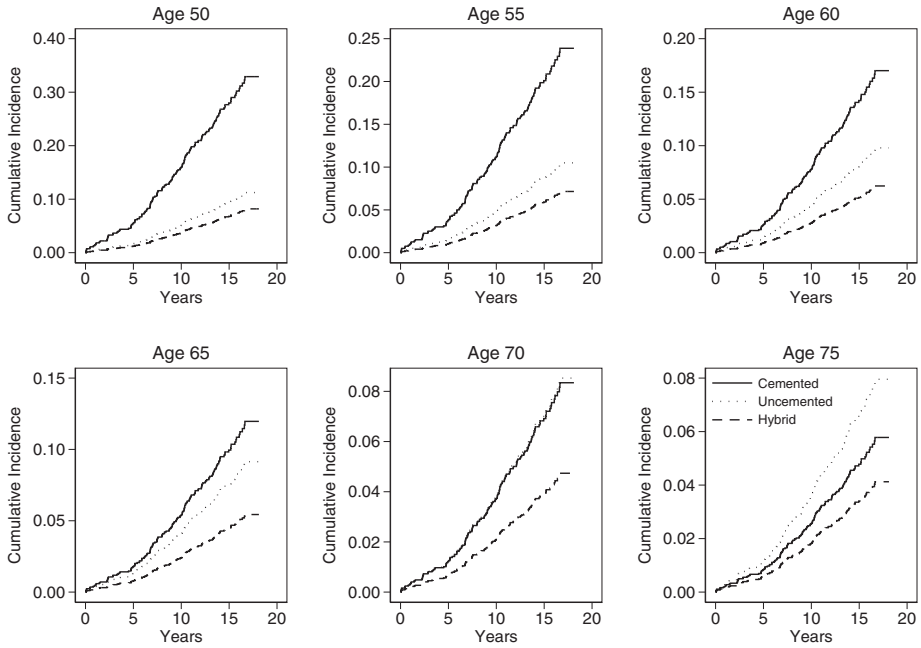

Fig. 2. Revision for loosening, wear, and osteolysis: unadjusted competing risk regression with death and revision for other reasons as competing risks.

Table 3
Subhazard ratios (SHRs) for All-Cause Revision and Revision for Loosening, Wear, and Osteolysis at Varying Ages. Fully Adjusted Model Includes Gender, Bearing Combinations, Hospital, Approach, and Surgeon Grade.

Outcome		Age	Between-Group *P* Value	Age-Group Interaction *P* Value	Hybrid	Uncemented	Cemented
					SHRs	SHRs (95% CI)	SHRs (95% CI)
All-cause revisions	Unadjusted		**.038**		1.00	1.39 (0.76-2.55)	**1.74 (1.13-2.67)**
	Adjusted for age			**.007**			
		50			1.00	1.12 (0.57-2.18)	**4.84 (2.76-8.49)**
		55			1.00	1.21 (0.64-2.29)	**3.83 (2.41-6.10)**
		60			1.00	1.32 (0.64-2.74)	**3.03 (1.94-4.74)**
		65			1.00	1.44 (0.57-3.61)	**2.40 (1.44-4.02)**
		70			1.00	1.56 (0.49-4.98)	**1.90 (1.00-3.62)**
		75			1.00	1.70 (0.41-7.03)	1.51 (0.68-3.37)
	Fully adjusted			**.007**			
		50			1.00	1.39 (0.67-2.91)	**4.67 (2.48-8.77)**
		55			1.00	1.49 (0.72-3.09)	**3.68 (2.10-6.43)**
		60			1.00	1.60 (0.70-3.65)	**2.89 (1.66-5.05)**
		65			1.00	1.71 (0.63-4.65)	**2.28 (1.22-4.26)**
		70			1.00	1.84 (0.55-6.19)	1.80 (0.85-3.79)
		75			1.00	1.97 (0.46-8.44)	1.41 (0.58-3.47)
Loosening, wear, and osteolysis	Unadjusted		**<.001**		1.00	1.09 (0.45-2.65)	**2.57 (1.46-4.53)**
	Adjusted for age			**<.001**			
		50			1.00	0.66 (0.26-1.65)	**6.63 (3.52-12.51)**
		55			1.00	1.05 (0.43-2.56)	**5.98 (3.30-10.84)**
		60			1.00	1.68 (0.65-4.37)	**5.39 (2.90-10.03)**
		65			1.00	2.70 (0.91-8.03)	**4.86 (2.40-9.82)**
		70			1.00	**4.32 (1.20-15.54)**	**4.38 (1.92-10.01)**
		75			1.00	**6.92 (1.54-31.04)**	**3.95 (1.49-10.47)**
	Fully adjusted			**<.001**			
		50			1.00	0.92 (0.30-2.79)	**6.07 (2.88-12.80)**
		55			1.00	1.39 (0.48-4.08)	**5.36 (2.60-11.04)**
		60			1.00	2.12 (0.70-6.43)	**4.73 (2.22-10.09)**
		65			1.00	3.22 (0.95-10.84)	**4.17 (1.80-9.70)**
		70			1.00	**4.88 (1.24-19.26)**	**3.68 (1.40-9.68)**
		75			1.00	**7.41 (1.55-35.49)**	**3.25 (1.07-9.90)**

Bold denotes the statistical significance ($P < .05$).
CI, confidence interval.

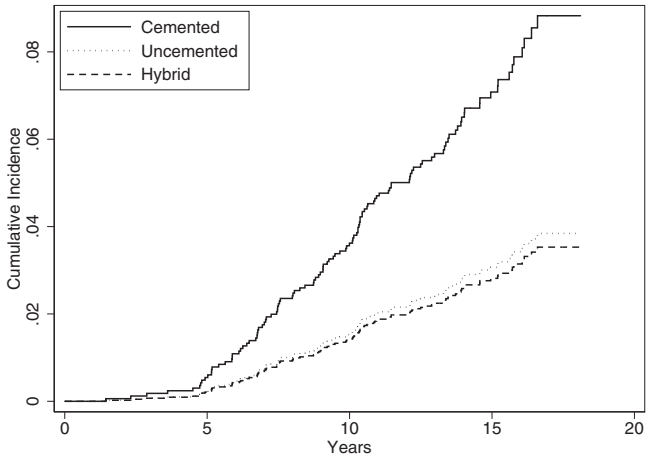

Fig. 3. All-cause revision at differing ages: competing risk regression with death as competing cause. Fully adjusted model includes gender, bearing combinations, hospital, approach, and surgeon grade.

Revision for Loosening, Wear, and Osteolysis

Again there was an age-cementing interaction with evidence that cemented had higher risk compared to hybrid at all ages (SHRs between 3.95 and 6.63, all $P \leq .006$; Table 2). Cemented fixation had a higher risk of revision than uncemented at ages 50, 55, and 60 (SHRs between 3.2 and 10.1, all $P \leq .004$).

Adjusting for gender, bearing combinations, hospital, approach, and surgeon level again did not alter the pattern of results (Fig. 4, Table 2). Cemented fixation had higher risk than hybrid at all ages (SHRs, 3.25-6.07) and a higher risk compared to uncemented at age 50 (SHRs, 6.61; $P < .002$) and age 55 (SHRs, 3.84; $P = .026$). Uncemented THA had a significantly higher risk than hybrid at ages 70 and 75 (SHRs, 4.88, 7.41). No other comparisons between uncemented THA and hybrid or cemented THA reached statistical significance. None of the other variables in the model were statistically significant.

Discussion

We have shown that cemented THA has the highest revision rate and hybrid THA has the lowest revision rates at 18 years in all age-groups when using the competing risk of death. This study confirmed our observation that loosening of cemented acetabulae is the most frequent cause of revision. There was an increased rate of revision for aseptic loosening, wear, and osteolysis in the cemented group even in patients aged 75 years at surgery. Uncemented fixation had an advantage over cemented fixation in patients aged 60 and younger. At no age did uncemented THA have improved survivorship compared with hybrids. These findings give support to the use of hybrid fixation for THA which combines the advantages of an uncemented acetabular component with a cemented stem and helps justify the decrease in the use of all-cemented fixation to less than 10% seen in New Zealand [8]. The Public Hospital cement-only policy gave an opportunity to perform this study. Although based on evidence available at the time, it appears to have contributed to additional revision procedures primarily for acetabular loosening in patients aged less than 65 years by removing surgeon choice.

The superior performance of uncemented cups in this series is at odds with the published literature. Clement et al in a comprehensive literature review, including registry results, concluded that the overall survival of cemented cups was superior to the uncemented alternatives and it remained the optimal mode of fixation for older patients due to predictable outcome and lower cost. They concluded that there was no significant evidence that younger patients benefit from uncemented cups [14]. Howard et al summarized the results using different uncemented cups over 20 years. All systems showed increasing numbers of revision in the second

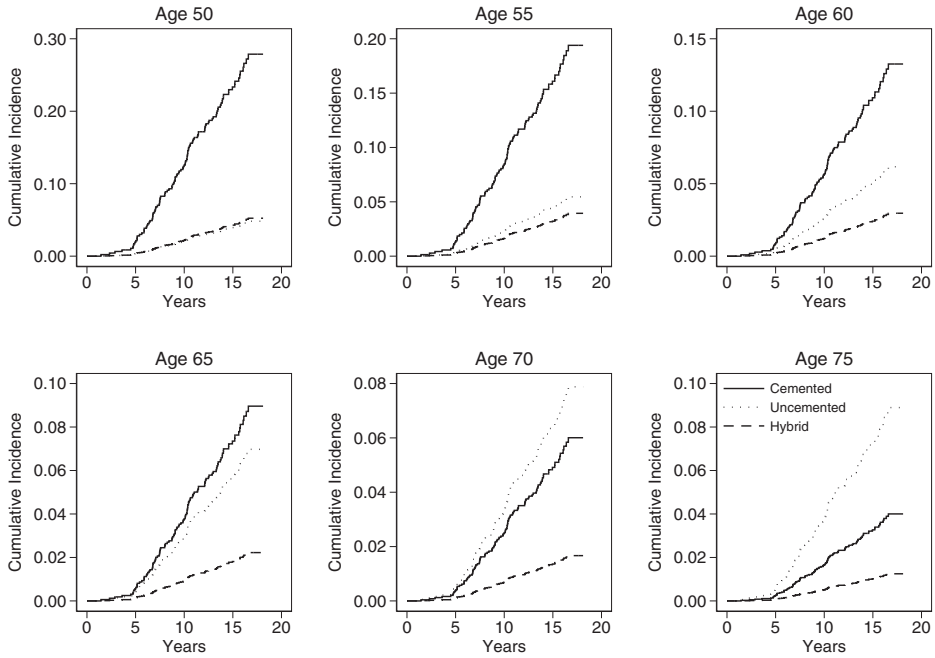

Fig. 4. Revision for loosening, wear, and osteolysis at differing ages: competing risk regression with death and revision for other causes as competing risk. Fully adjusted model includes gender, bearing combinations, hospital, approach, and surgeon grade.

decade with none of the newer implants showing significant improvements [7]. Hallan et al [6] reported 81%-92% survival of uncemented cups at 10 years with few problems until 7 years, but no system had satisfactory long-term results.

Makela et al [16] summarized the results of the combined Nordic registries. Cemented hips had the best survivorship at 10 years in all ages from 55 years and older and were significantly better than hybrids. They found increased risk of early revision with uncemented due to fracture or early aseptic loosening and concluded that the increasing use of uncemented implants in patients over 65 years was not supported [16]. A recent meta-analysis concluded that there is a tendency toward improved outcomes with cemented compared to both uncemented and hybrid fixation [17]. However, the studies included in the analysis all contained older prosthesis, some of which are no longer in use, and therefore results may not represent those of modern prostheses.

The NZJR still reports that cemented cups have the lowest revision rate and have improved survivorship at all time periods out to 18 years with 86.1% survival for cemented, 84.5% for uncemented, and 84.1% for hybrid hips [8]. For comparison, the Kaplan-Meier (KM) revision-free rates in our series were 83.3% (cemented), 92.3% (uncemented), and 90.7% (hybrid) at 18 years. The difference appears to be due to the improved survival of uncemented acetabular components in our series rather than the poor performance of cemented cups.

In this study, we used competing risk regression, which gives a more relevant estimate of revision rates than the KM analysis. In a competing risk regression, if a patient dies it precludes the chance of them having a revision. Similarly, revision for another reason also precludes the chance of a cause-specific revision [18–20]. In younger patients with low death rates even at long-term follow-up, it more closely approximates the KM figure than in older patients where the KM figure may overestimate revision rates. Despite this, we still showed that cemented fixation was associated with higher revision rates than hybrid fixation even in older patients.

Age is a determinant of outcome with younger age associated with poorer outcomes and survivorship of 30%-61% at 20-25 years [21–23]. Sochart and Porter [21] reported 54% survival at 25 years in patients under 40 years of age using cemented Charnley implants. Swarup et al [22] found no difference between cemented and uncemented implants in patients under 35 years. While Corten et al [23] reported improved survival with uncemented fixation (56%) compared with cemented fixation (30%) at 20 years in patients under 65 years. Our revision rate of approaching 35% for cemented cups in younger age-groups compares quite favorably with these reports. The revision rate for hybrid THA remained relatively constant for all ages and was less than 10% even at age 50 years.

The NZJR has shown differing revision rates between component fixation when stratified by age [8]. Cemented hips perform better than hybrids and uncemented in the over 75-year age-group. Uncemented hips have significantly lower revision rates than hybrid in the under 55 age-group and higher rates than both cemented and hybrids in the over 75-year-old group. Hybrid hips have significantly lower revision rates than cemented hips for patients aged 64 and under and no significant difference in those 65-74 years [8,24]. We saw a similar pattern with hybrids having lower rates than cemented but found no evidence that hybrid fixation was worse than cemented in patients older than 75 years.

In contrast, the Norwegian Joint Replacement Register found no significant age stratification [25]. Both cementless and hybrid fixation had significantly higher relative risks of revision compared to cemented fixation across 1987 to 2016 (relative risk = 1.32 and 1.22, respectively); however, when analyzing the data based on modern prostheses and new surgical techniques (2006-2016), there were no significant differences [25]. In the combined Nordic registries, hybrid fixation had worse 10-year survivorship than cemented or uncemented in patients aged younger than 55 years (68.5% vs 77.4% cemented, 75.6% uncemented) and aged 55-64 years (90.0% vs 92.2%, 91.8%) [26]. We found similar survivorship for cemented cups but much improved results with the hybrid group.

The England and Wales Joint Registry report that cemented THA had the lowest rate of revision at 14 years (4.88%) with hybrid THA (5.38%) and uncemented the highest (8.9%). However, hybrid hips had the lowest revision rate in patients under 65 years and the lowest rates of aseptic loosening [9]. The Australian Joint Registry limited their analyses in the 2017 reports to exclude those using conventional polyethylene and metal-on-metal combinations [10]. Hybrid fixation with modern bearing surfaces had a cumulative revision rate of 6% at 16 years [10]. They found no difference between fixation type in patients under 65 years, while uncemented fixation had higher revision rates than hybrid in patients over 65 years, and higher than both cemented and hybrid in patients older than 75 years. Our series differs in that we are reporting the use of conventional polyethylene which has inferior long-term results to highly cross-linked polyethylene.

Strengths and Limitations

Strengths of this study are that it is a large single-center series which helps to reduce some of the confounders inherent in pooled registry data such as multiple implant combinations, differing modes of failure at different time intervals, varying bearing surfaces and head sizes, surgeon variation, and failure to report all revisions. It has long-term results up to 18 years which is important as many implants start to fail after 10 years. There were relatively low rates of revision for infection and dislocation so these results are more likely to represent the results of implant and fixation choice. The surgeons were all experienced in cemented and uncemented techniques.

A limitation is that this is an observational study and the groups were not randomized. Therefore, residual confounding from other variables not included in our adjusted models, such as comorbidities, cannot be ruled out. We have good survivorship data from our NZJR and local audit databases but do not have clinical and radiological evidence for all hips, which would be unrealistic in a study group of this size.

The cement-only policy allowed us to compare cemented THA with the uncemented and hybrid groups with little selection bias. However, there was potentially significant selection bias between the uncemented and hybrid groups. The uncemented group was relatively small compared with the other groups, which meant that despite apparently large SHRs the results did not reach statistical significance due to wide confidence intervals. Therefore, it is only possible to conclude that hybrid THA did not show any statistically significant advantage over uncemented THA except for revision for wear, loosening, and osteolysis in older patients. However, uncemented THA did show an advantage over cemented THA in younger patients. Larger studies and longer-term follow-up is required to determine whether there are significant differences between hybrid and uncemented THA.

Many different implant combinations were used and not all implants within a class may perform equally [27,28]. The polished Exeter stem and Muller straight stem have excellent results but good cementing technique is critical. Some of the other cemented stems used in this series such as the Spectron (Smith & Nephew, Memphis, TN) have been less successful [8].

Conventional polyethylene and 28-mm heads were used in the majority of cases. Very few large head sizes or hard-on-hard bearings more commonly used in uncemented systems were used. Not all of these combinations have been successful and can confound registry results. Conventional polyethylene is rarely used these days

so the results may not be generalizable to modern practice; however, the use of cross-linked polyethylene may be expected to improve results in all groups.

Conclusion

Hybrid THA, when using conventional polyethylene, showed improved long-term survival over cemented fixation at all ages and some advantage over uncemented fixation at older ages. Cemented fixation remains a reasonable option in those patients aged 70 and over, but there was still a higher risk of revision for aseptic loosening, wear, or osteolysis. Uncemented THA did not show any statistically significant advantage over hybrid fixation but did show an advantage over cemented THA in younger patients. This gives support for the trend toward increased use of uncemented fixation of the acetabulum.

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■ HIP

Cemented or uncemented acetabular fixation in combination with the Exeter Universal cemented stem

LONG-TERM SURVIVAL TO 18 YEARS

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Aims

To compare long-term survival of all-cemented and hybrid total hip arthroplasty (THA) using the Exeter Universal stem.

Methods

Details of 1,086 THAs performed between 1999 and 2005 using the Exeter stem and either a cemented (632) or uncemented acetabular component (454) were collected from local records and the New Zealand Joint Registry. A competing risks regression survival analysis was performed with death as the competing risk with adjustments made for age, sex, approach, and bearing.

Results

There were 61 revisions (9.7%; 0.82 revisions/100 observed component years, (OCYs)) in the all-cemented group and 18 (4.0%; 0.30/100 OCYs) in the hybrid group. The cumulative incidence of revision at 18 years was 12.1% for cemented and 5.2% for hybrids. There was a significantly greater risk of revision for all-cemented compared with hybrids (unadjusted sub-hazard ratio (SHR) 2.44; p = 0.001), and of revision for loosening, wear, or osteolysis (unadjusted SHR 3.77; p < 0.001). After adjustment, the increased risk of all-cause revision did not reach significance at age 70 years and above. The advantage for revision for loosening, wear, and osteolysis remained at all ages.

Conclusion

This study supports the use of uncemented acetabular fixation when used in combination with the Exeter stem with improved survivorship for revision for aseptic loosening, wear, and osteolysis at all ages and for all-cause revision in patients less than 70 years.

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Introduction

The Exeter cemented stem (Stryker, Kalamazoo, Michigan, USA) has excellent long-term results with survivorship for aseptic loosening approaching 100% at long-term follow-up.[1-4] Cemented acetabular components have not been as successful but excellent results can be achieved.[5,6]

In recent years, there has been an increasing trend towards the use of uncemented or hybrid fixation. Uncemented acetabular components are now used in 72% of total hip arthroplasties in England, Wales, Northern Ireland, and the Isle of Man, and over 90% in Australia and New Zealand.[7-9] Improvements in design and locking mechanisms, options for screw fixation, and alternative bearing surfaces may have contributed to this change. The hybrid construct may combine the advantages of a cemented stem with the benefits of an uncemented acetabular component and has been recommended as the best option for all age groups.[7,10] However, registry studies,[7-9,11] meta-analyses,[12,13] and reviews[14] continue to show an advantage for cemented components over hybrid or uncemented constructs. Excellent long-term results have been reported with monoblock acetabular components,[15,16] but long-term studies with other designs of modular uncemented acetabular components have been disappointing.[17,18]

The Exeter Universal stem has been used in combination with both cemented and uncemented acetabular components in our centre. Our observation has been that cemented acetabular

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Table I. Details of hip arthroplasty procedures including place of surgery, fixation, age, original diagnosis, sex, approach, and deaths during the study period.

Characteristic	Public (n = 698)		Private (n = 388)		Total (n = 1,086)	
	Cemented	Hybrid	Cemented	Hybrid	Cement	Hybrid
Total, n (%)	565 (80.9)	133 (19.1)	67 (17.3)	321 (82.7)	632 (58.2)	454 (41.8)
OA, n (%)	506 (89.6)	99 (74.4)	60 (89.6)	298 (92.8)	566 (89.6)	397 (87.4)
AVN, n (%)	20 (3.5)	5 (3.8)	0 (0.0)	6 (1.9)	20 (3.2)	11 (2.4)
Dysplasia, n (%)	5 (0.9)	10 (7.5)	1 (1.5)	8 (2.5)	6 (0.9)	18 (4.0)
RA/inflammatory, n (%)	19 (3.4)	13 (9.8)	3 (4.5)	4 (1.2)	22 (3.5)	17 (3.7)
Old trauma, n (%)	8 (1.4)	1 (0.8)	2 (3.0)	5 (1.6)	10 (1.6)	6 (1.3)
Perthes/SUFE, n (%)	3 (0.5)	5 (3.8)	0 (0)	0 (0)	3 (0.5)	5 (1.1)
Pagets, n (%)	2 (0.4)	0 (0)	0 (0)	0 (0)	2 (0.3)	0 (0.0)
Septic arthritis, n (%)	2 (0.4)	0 (0)	1 (1.5)	0 (0)	3 (0.5)	0 (0.0)
Mean age, yrs (range)	68.0 (30 to 88)	53.7 (15 to 77)	70.6 (42 to 82)	62.1 (35 to 81)	68.3 (30 to 88)	59.7 (15 to 81)
Age bands/years, n (%)						
15 to 39	2 (14.3)	12 (85.7)	0 (0)	5 (100.0)	2 (0.3)	17 (3.7)
40 to 49	16 (36.4)	28 (63.6)	4 (33.3)	8 (66.7)	20 (3.2)	36 (7.9)
50 to 59	76 (58.5)	54 (41.5)	0 (0)	89 (100.0)	76 (12.0)	143 (31.5)
60 to 69	214 (86.6)	33 (13.4)	13 (7.0)	172 (93.0)	227 (35.9)	205 (45.2)
70 to 79	207 (97.2)	6 (2.8)	47 (51.1)	45 (48.9)	254 (40.2)	51 (11.2)
80+	50 (100.0)	0 (0)	3 (60.0)	2 (40.0)	53 (8.4)	2 (0)
Male sex, n (%)	238 (42.1)	71 (53.4)	28 (41.8)	185 (57.6)	266 (42.1)	256 (56.4)
Approach posterior, n (%)	294 (52.0)	80 (60.2)	17 (25.4)	83 (25.9)	311 (49.2)	163 (35.9)
Deaths, n (%)	237 (41.9)	13 (9.8)	21 (31.3)	60 (18.7)	258 (40.8)	73 (16.1)

AVN, avascular necrosis; OA, osteoarthritis; RA, rheumatoid arthritis; SUFE, slipped upper femoral epiphysis.

components start to fail due to aseptic loosening in the second decade after total hip arthroplasty (THA), while it has been very rare to see femoral loosening or uncemented acetabular component failure. A previous study from our institution has shown an advantage to hybrid fixation over all cemented THA, but this included a number of cemented implants known to have poor long-term survivorship.[19]

The purpose of this observational study was to compare the long-term survival of cemented and hybrid THA using the Exeter stem at mean 15 year follow-up.

Methods

Our public hospital services around 200,000 patients spread over a large geographical area with one major city of 140,000 and a large rural population. There is also a private hospital with the majority of surgeons operating at both hospitals. Cost constraints and a desire to follow evidence-based practice led us to developing a cement-only policy between 1999 and 2005 in our public hospital, with exceptions only allowed after discussion at a departmental meeting. There was unrestricted choice at our private hospital. We identified 1,086 THAs that were performed by eight consultant surgeons using the Exeter Universal stem performed between July 1999 and December 2005 at either hospital from databases cross referenced to the New Zealand Joint Registry (NZJR).[7] We excluded THA for acute hip fracture but included all other indications for surgery. Our departmental database was used to search for any revision procedure including excision arthroplasty and cross-referenced to the NZJR. All reasons for revision were checked through use of electronic patient charts and radiological records.

The patient demographic details and implants used are detailed in Tables I and II.

Table II. Acetabular implants used and numbers and proportion revised.

Implant	Company	Implants, n	Revised, n (%)
Cemented			
Total	N/A	632	61 (9.7)
Contemporary	Stryker	476	49 (10.3)
Muller PE	Zimmer	114	7 (6.1)
Reflection All Poly	Smith & Nephew	27	1 (3.7)
Charnley	DePuy Synthes	10	2 (20.0)
Exeter	Stryker	5	2 (40.0)
Uncemented			
Total	N/A	454	18 (4.0)
Morscher	Sulzer	285	12 (4.2)
Fitmore/Fitek	Zimmer	66	2 (3.0)
RM press fit	Mathys	33	2 (6.1)
Reflection	Smith & Nephew	30	0 (0.0)
Trident	Stryker	30	1 (3.3)
Others	N/A	10	1 (10.0)

N/A, not applicable.

Osteoarthritis (OA) was the diagnosis in 963 (89%) of hips. A cemented acetabular component was used in 632 hips (58%) and an uncemented device in 454 (42%). Of the 1,086 hips, 610 (56%) were performed via a lateral approach and 474 (44%) via a posterior approach. Two hips underwent a trochanteric osteotomy and were included in the lateral group for statistical analysis.

Surgical technique. The Exeter Universal stem was used throughout the study period. The taper changed to the V40 taper in 2001. Antibiotic-containing Simplex bone cement (Stryker) was used routinely with vacuum mixing and insertion using a cement gun with proximal cement pressurization.

The acetabulum was prepared for cemented components by power reaming. Pits and multiple drill holes were made with the

Table III. Details of revisions by hospital and fixation, reason for revision, and original diagnosis.

Reason for revision (with primary diagnosis), n	Public hospital (n = 698)		Private hospital (n = 388)		Total	
	Cemented (n = 565)	Hybrid (n = 133)	Cemented (n = 67)	Hybrid (n = 321)	Cemented (n = 632)	Hybrid (n = 454)
Acetabular loosening	41	2	3	N/A	44	2
Acetabular and femoral loosening	2	1	N/A	N/A	2	1
Femoral loosening	N/A	2	N/A	3	N/A	5
Wear and/or osteolysis	1	N/A	N/A	1	1	1
Total loosening, wear, osteolysis, n (%)	44 (7.8)	5 (3.8)	3 (4.5)	4 (1.2)	47 (7.4)	9 (2.0)
OA	40	3	1	2	41	5
AVN	N/A	N/A	N/A	1	N/A	1
Dysplasia	N/A	N/A	N/A	1	N/A	1
RA/inflammatory	2	2	1	N/A	3	2
Old trauma	N/A	N/A	1	N/A	1	N/A
Perthes/SUFE	1	N/A	N/A	N/A	1	N/A
Pagets	N/A	N/A	N/A	N/A	N/A	N/A
Septic arthritis	1	N/A	N/A		1	N/A
Dislocation, n (%)	4 (0.7)	2 (1.5)	0	2 (0.6)	4 (0.6)	4 (0.9)
OA	3	1	N/A	1	3	2
RA/inflammatory	1	1	N/A	N/A	1	1
AVN	N/A	N/A	N/A	1	N/A	1
Femur fracture (all OA)	4 (0.7)	1 (0.8)	1 (1.5)	3 (0.9)	5 (0.8)	4 (0.9)
Infection (all OA)	5 (0.9)	0	0	0	5 (0.8)	0
Pain (OA)	N/A	N/A	N/A	1	0	1
Total, n (%)	57 (10.1)	8 (6.0)	4 (6.0)	10 (3.1)	61 (9.7)	18 (4.0)
Mean time to revision, yrs (range)	9.5 (0.8 to 16.7)	9.2 (2.9 to 14.5)	10.1 (4.8 to 15.2)	8.5 (0.5 to 13.7)	9.6 (0.8 to 16.7)	8.8 (0.5 to 14.5)

AVN, avascular necrosis; N/A, not applicable; OA, osteoarthritis; RA, rheumatoid arthritis; SUFE, slipped upper femoral epiphysis.

aim of producing a porous bed of bone for cement engagement. Medial wall bone graft was used as required. Cement was pressurized using a commercially available pressurizer. Polymethylmethacrylate (PMMA) beads were present on the Reflection All Poly (Smith & Nephew, Memphis, Tennessee, USA) and Contemporary acetabular components (Stryker), but not on the Muller low profile PE (Zimmer, Winterthur, Switzerland) or Charnley (DePuy Synthes, Warsaw, Indiana, USA) designs. All the cemented acetabular implants were made from conventional polyethylene.

For uncemented acetabular components a press fit was obtained usually by under-reaming by 1 mm to 2 mm. Supplementary screws were used if required but were not used for the nonmodular implants (Morscher (Sulzer Orthopaedics, Baar, Switzerland) and RM Pressfit (Mathys, Bettlach, Switzerland)). Polyethylene inserts were almost all conventional polyethylene. Highly cross-linked polyethylene was introduced in 2003 for the Fitmore acetabular component (Zimmer) but only used in 36 hips.

The acetabular implants used are detailed in Table II. The femoral head size was 28 mm in 1,065 hips (98%), 22 mm in 19 (1.8%), and 36 mm in two hips (0.2%). The head material was stainless steel in 902 hips (83%) and alumina ceramic in 184 (17%).

Statistical methods. Appropriate summary statistics were calculated for all variables of interest. Associations between categorical variables were investigated using chi-squared tests where at least 80% of cells had expected counts of five or more, and Fisher's exact tests otherwise. Comparisons of continuous variables between two groups were performed using Mann-Whitney U tests where data were not normally distributed within each group. These analyses ignored the clustering resulting from multiple procedures (left and right hips) for some patients.

Survival analysis was performed using revision for any reason as the primary endpoint with aseptic loosening, wear, or osteolysis as a secondary endpoint. Competing risks survival analysis with death as a competing risk was used for all-cause revision analyses. Death and revision for other reasons were used as competing risks for models investigating revision for wear, aseptic loosening, and osteolysis. The number of estimated coefficients was constrained by the limited number of revision events. Adjustments were made for age (as a continuous variable which was allowed to interact with cementing group), sex (for all-cause revision only), approach (posterior versus other, for all-cause revision only), and bearing surface. An exploratory analysis adding public/private hospital and surgeon grade did not change the statistical significance of the results presented. Multiple procedures on the same patient (left and right hips) were accommodated by using robust clustered (by patient) standard errors. Cumulative incidence curves were used to show differences between cementing groups, including at selected ages in the models. Analyses were performed using Stata 15.1 (StataCorp, College Station, Texas, USA) with a two-sided p-value < 0.05 considered statistically significant.

Results

The mean follow-up was 14.8 years (11.6 to 18.3). The hybrid group was younger than the cemented group by eight years ($p <$

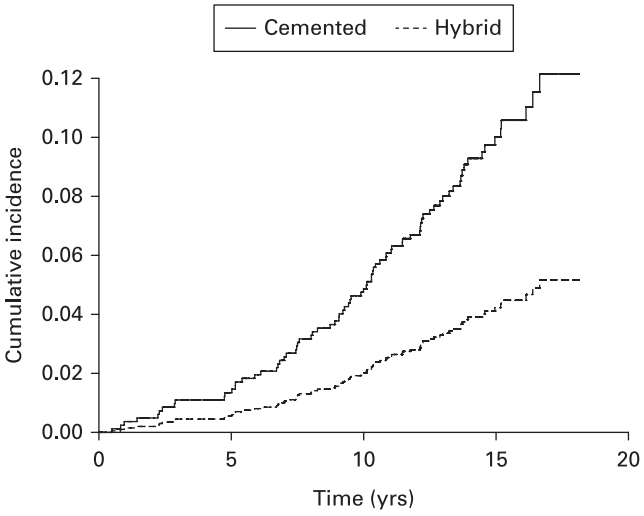

Fig. 1

Cumulative incidence graph comparing all-cause revision (unadjusted) with death as competing risk.

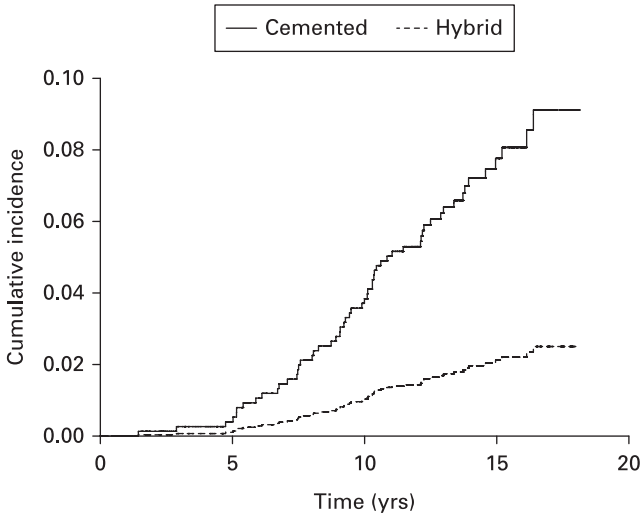

Fig. 2

Cumulative incidence graphs showing cumulative risk of revision for loosening, wear, or osteolysis (unadjusted) with death as competing risk.

0.001, Mann-Whitney U test) and there were more males. Additionally, they were more likely to have been treated via a lateral approach and were less likely to have died than the cemented group (all $p < 0.001$, chi-squared test). There was no statistically significant difference in original diagnosis between groups with the exception of acetabular dysplasia which was significantly higher in the hybrid group ($p < 0.001$, chi-squared test).

In the public hospital group, 565 hips (80.9%) were cemented and 133 (19.1%) were hybrid. In contrast, 67 (17.3%) were cemented in the private hospital group and 321 (82.7%) were hybrid ($p < 0.001$, chi-squared test). The public hospital patient group were significantly older than the private hospital group (mean 65.3 versus 63.6 years; $p < 0.001$, Mann-Whitney U test).

In the public hospital group there were more females, a higher proportion of patients underwent a posterior approach, and more patients had died (all $p < 0.001$, chi-squared test) than in the private hospital group. A higher proportion of patients had rheumatoid or inflammatory arthritis ($p = 0.018$, chi-squared test) and a lower proportion of patients had OA ($p = 0.005$, chi-squared test). There was no significant difference between groups for any other diagnosis. Trainees under direct supervision (consultant scrubbed) performed 253 hips in the public hospital (236 cemented, 17 hybrid). Consultant surgeons performed all 388 cases at the private hospital.

The revision rate for trainees (17 of 253, 6.7%) was not significantly different from consultants (62 of 833, 7.4%; $p = 0.698$, chi-squared test). For cemented hips, trainees had lower rates of all-cause revision (16 of 236, 6.8%) than consultants (45 of 396, 11.4%) but this did not reach significance ($p = 0.059$, chi-squared test).

In total, 79 hips were revised, 18 (4.0%) in the hybrid group and 61 (9.7%) in the all-cemented group ($p < 0.001$, chi-squared test). This gave a revision rate for the entire cohort of 0.58/100 observed component years (OCYs) (exact 95% confidence interval (CI) 0.46 to 0.72). There was a significantly lower rate of revision in the hybrid group (0.30 revisions/100 OCYs) compared to the cemented group (0.82/100 OCYs). In the hybrid group there were six isolated acetabular revisions, one liner exchange, six isolated femoral revisions, and five with all components revised. In the cemented group there were 43 isolated acetabular revisions, 14 all component revisions, three femur only, and one modular head exchange.

The commonest reason for revision was loosening of cemented acetabular components. This accounted for 46 of 61 (75.4%) revisions in the cemented group. There were eight revisions for femoral loosening (0.8% of all hips) of which three also had acetabular loosening with no statistical difference between cemented and hybrid groups ($p = 0.074$, Fisher's exact test). There was a significantly higher revision rate for loosening, wear, and osteolysis in the cemented group (47 of 632, 7.4%) than the hybrid group (9 of 454, 1.8%; $p < 0.001$, chi-squared test). There was no significant difference seen between the groups for revision for deep infection ($p = 0.079$, Fisher's exact test), dislocation ($p = 0.726$, Fisher's exact test), or femoral fracture ($p = 1.000$, Fisher's exact test). Detailed reasons for revision are given in Table III.

The acetabular components used and numbers that were subsequently revised are listed in Table II. There were no significant differences seen in the proportion revised between implants in the cemented group ($p = 0.057$, Fisher's exact test) or between monoblock and modular acetabular components in the hybrid group ($p = 0.640$, Fisher's exact test).

Survivorship. There was evidence of increased risk of all-cause revision for the cemented group (unadjusted sub-hazard ratio (SHR) 2.44, 95% CI 1.44 to 4.15, $p = 0.001$) using competing risk analysis (Figure 1). The cumulative incidence of revision at 18 years was 5.2% for the hybrid group and 12.1% for the all cemented group. Kaplan-Meier revision-free rates, ignoring the competing risk of death, at 18 years were: hybrid 95.0% (95% CI 92.1% to 96.9%); and cemented 82.0% (95% CI 75.8% to

Table IV. Sub-hazard ratios with 95% confidence intervals for all-cause revision and revision for loosening, wear, and osteolysis at varying ages. Fully adjusted model includes age, sex, bearing combinations, and approach.

Outcome	Between-group p-value	Age-group interaction p-value	Hybrid SHR	Cemented unadjusted, SHR (95% CI)	Cemented fully adjusted, SHR (95% CI)
All-cause revisions					
All ages	0.001	0.095	1.00	2.44 (1.44 to 4.15)	N/A
Age-specific, yrs					
45	N/A	N/A	1.00	7.14 (3.08 to 16.57)	7.24 (2.99 to 17.54)
50	N/A	N/A	1.00	5.72 (2.95 to 11.11)	5.69 (2.82 to 11.47)
55	N/A	N/A	1.00	4.58 (2.63 to 7.98)	4.47 (2.48 to 8.06)
60	N/A	N/A	1.00	3.67 (2.10 to 6.41)	3.51 (1.94 to 6.34)
65	N/A	N/A	1.00	2.94 (1.51 to 5.74)	2.75 (1.36 to 5.59)
70	N/A	N/A	1.00	2.36 (1.01 to 5.51)	2.16 (0.89 to 5.28)
75	N/A	N/A	1.00	1.89 (0.65 to 5.46)	1.70 (0.56 to 5.17)
80	N/A	N/A	1.00	1.51 (0.41 to 5.51)	1.33 (0.34 to 5.16)
85	N/A	N/A	1.00	1.21 (0.26 to 5.61)	1.05 (0.21 to 5.20)
Loosening, wear, and osteolysis					
All ages	< 0.001	0.625	1.00	3.77 (1.83 to 7.75)	N/A
Age-specific, yrs					
45	N/A	N/A	1.00	9.09 (3.87 to 21.35)	8.67 (3.72 to 20.21)
50	N/A	N/A	1.00	8.57 (3.95 to 18.60)	8.28 (3.80 to 18.04)
55	N/A	N/A	1.00	8.09 (3.77 to 17.32)	7.90 (3.61 to 17.33)
60	N/A	N/A	1.00	7.63 (3.36 to 17.31)	7.55 (3.18 to 17.89)
65	N/A	N/A	1.00	7.19 (2.82 to 18.31)	7.21 (2.66 to 19.52)
70	N/A	N/A	1.00	6.78 (2.28 to 20.15)	6.88 (2.14 to 22.10)
75	N/A	N/A	1.00	6.40 (1.80 to 22.73)	6.57 (1.69 to 25.59)
80	N/A	N/A	1.00	6.03 (1.40 to 26.05)	6.27 (1.31 to 30.06)
85	N/A	N/A	1.00	5.69 (1.07 to 30.17)	5.99 (1.01 to 35.64)

CI, confidence interval; N/A, not applicable; SHR, sub-hazard ratio.

86.8%) with 18 patients (12 cemented and six hybrid) alive and revision free at this time.

There was also evidence of a greater risk of revision for loosening, wear, or osteolysis for the cemented group (unadjusted SHR 3.77, 95% CI 1.83 to 7.75; $p < 0.001$). The cumulative incidences at 18 years were 2.5% (hybrid) and 9.1% (cemented) (Figure 2).

There was no evidence of an interaction between age and cement group for all-cause revision (interaction $p = 0.095$) or revision for loosening, wear, or osteolysis (interaction $p = 0.625$). These remained nonsignificant with further adjustment (interaction $p = 0.080$ and interaction $p = 0.711$, respectively) (Table IV). There was a significantly increased risk of all-cause revision in the cemented group for all ages aside from 75 years and older. In the fully adjusted model the increased risk of revision in the cemented group was seen at all ages but did not reach significance at age 70 years and older (Table IV, Figure 3). For revision for loosening, wear, or osteolysis, a cemented acetabular component was associated with increased risk at all ages in both unadjusted and fully adjusted models (Table IV, Figure 4). None of the other variables in the model were statistically significant.

Discussion

This study has shown an increased rate of all-cause revision for cemented THA compared with hybrid THA when using the Exeter stem at long-term follow-up to 18 years. This was primarily due to loosening of cemented acetabular components. It was most marked in younger patients and did not reach significance for those aged 70 years or older. An increased rate of revision for loosening, wear, and osteolysis was seen at all ages. At no age was there evidence for superior performance of cemented over hybrid THA after adjusting for other variables.

We have previously demonstrated an advantage to hybrid fixation over cemented fixation but this study included a number of different cemented femoral components some of which such as the Spectron (Smith & Nephew, Memphis, Tennessee, USA) have performed poorly at longer term follow-up.[19] In contrast, the Exeter stem has excellent long-term survival with reported component survival of 92% to 100% in studies between 13 and 22 years, even in young patients.[1-3,20] However, in these series, the results for the acetabular component have been less successful with survival for all-cause revision of 81% to 91%.[1,2,20] Results are also poorer in younger patients with 75.7% survival for all-cause revision at 17 years reported in patients under the age of 40 years.[3]

Other authors have reported better results with cemented acetabular components. Maggs et al,[6] using the cemented Contemporary flanged acetabular component and Exeter stem in patients with a mean age of 70.5 years, reported no acetabular revisions for loosening. Eight acetabular components were revised for other reasons, giving 97.8% all-cause revision at 12.5 years. Radiolucent lines were seen in 36% of the surviving hips. Young et al[21] reported 94.4% overall survival at 13 years with the Charnley Ogee acetabular component and Exeter stem.

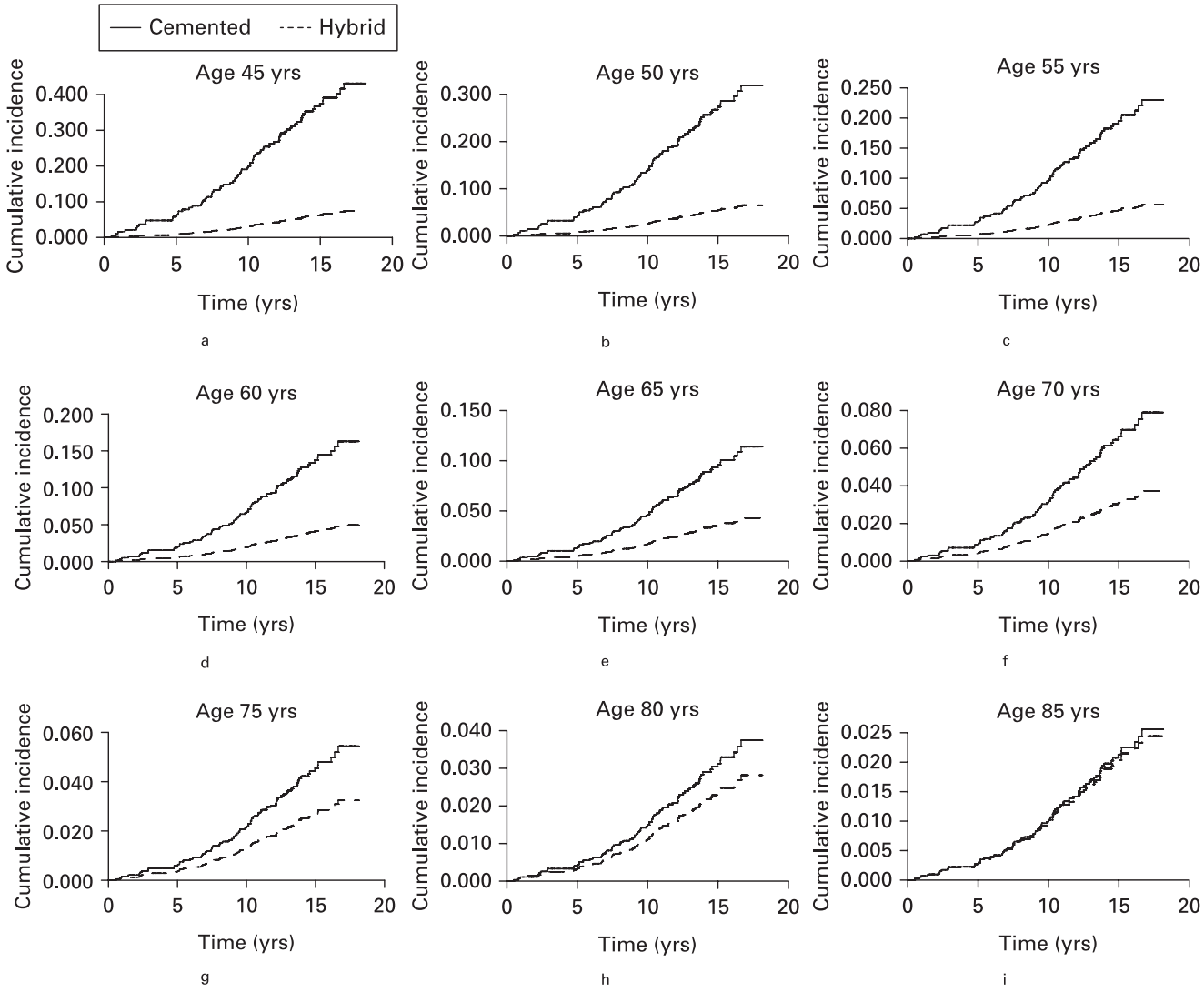

Fig. 3

Cumulative incidence of all-cause revision at differing ages (fully adjusted).

There are fewer long-term results of an uncemented acetabulum with the Exeter stem. Hook et al,[4] in a minimum ten-year review of patients with an Exeter stem and a mean age at surgery of 61 years, found excellent survival of the component but varying failure rates of both cemented and uncemented acetabular components with survivorship for any component revision around 60% at 15 years.[4]

Jameson et al,[22,23] in two studies from the England and Wales National Joint Registry (NJR), reported on the seven-year results of 34,721 THAs using the Exeter cemented Contemporary combination and the five-year results of 15,740 hybrid Trident/Exeter hips. A flanged Contemporary acetabular component had a seven-year revision rate of 1.16%, while a hooded Contemporary implant had a revision rate of 3.49% at seven years.[22] The Exeter/Trident combination showed a 1.56% risk of revision at five years.[23]

We found no significant differences in failure rates between any of the acetabular components. The main cemented acetabular components in our series were the hooded Contemporary and the Muller PE. Both have been widely used in New Zealand and have performed reasonably well. However, the NZJR does not distinguish between the hooded and flanged version of the Contemporary acetabular component.

Our Kaplan-Meier survivorship of 82% at 18 years for all-cause revision in the all-cemented group is similar to the previously mentioned studies but is poorer than the NZJR rate for fully cemented THA (86.2%).[7] We do not believe that the poor results of the cemented hips compared to the New Zealand general outcome are due to technical failures by the surgeons but more to do with the public hospital cemented policy. This led to disappointing results particularly in younger patients. This has also been the finding in the NZJR, where cemented THAs have a higher revision rate than either uncemented or hybrid THA in patients less than 64 years.[7]

The overall revision rate in this series of 0.58/100 OCYs compares favourably with the New Zealand general findings

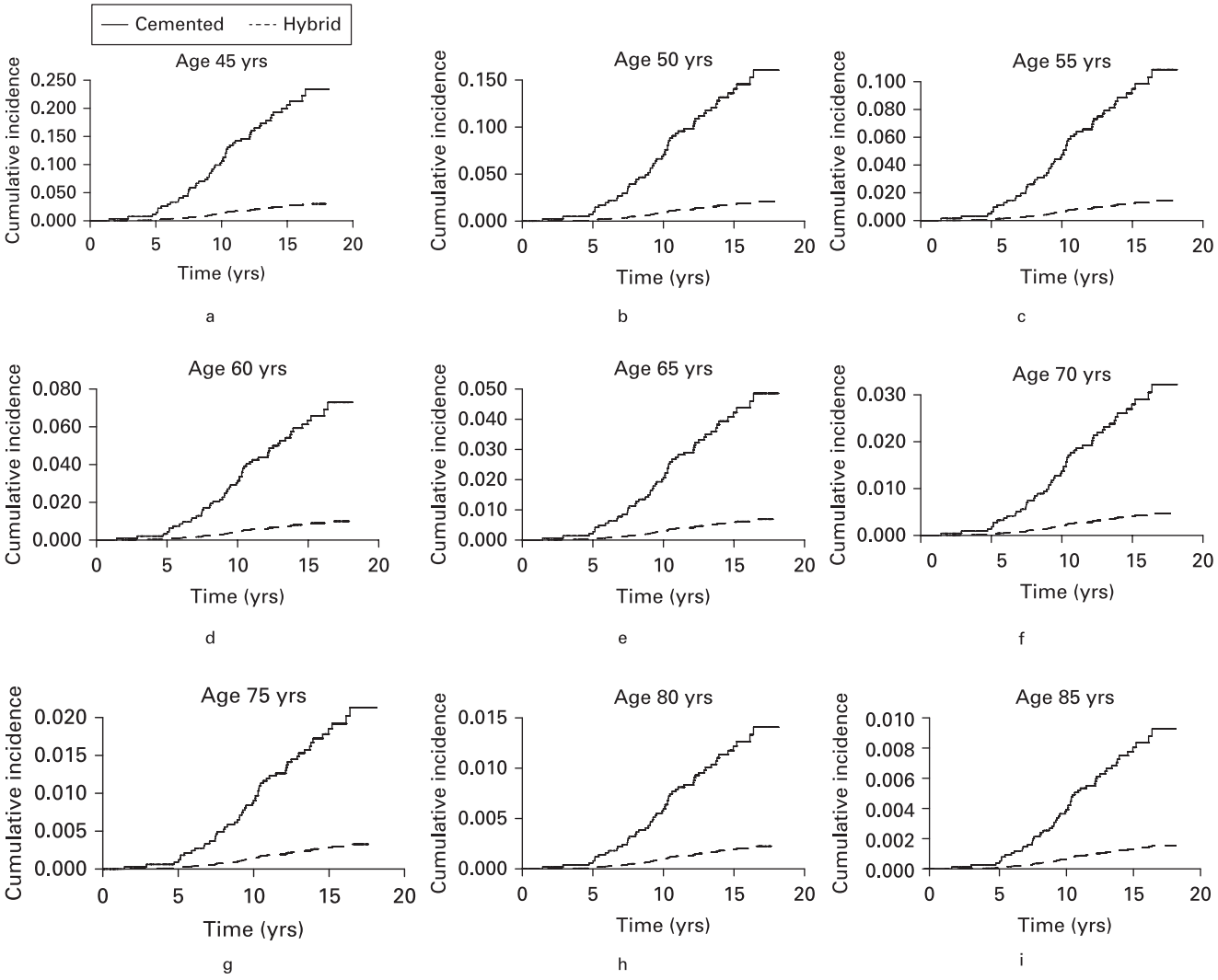

Fig. 4

Cumulative incidence of revision for loosening, wear and osteolysis at differing ages (fully adjusted).

of 0.73/100 OCYs (95% CI 0.71 to 0.73).[7] There were few early revisions for loosening and the mean time to revision for cemented hips was 9.6 years. Hanly et al[24] have recently suggested that the proficiency threshold for cemented acetabular components is greater than ten cases per year with the maximum benefit achieved for surgeons performing more than 25 cases per year. All the surgeons in our study were experienced in cementing techniques and during the study period, most surgeons performed more than 25 cemented acetabular implantations per year.

Our finding of improved survivorship of the hybrid over a fully cemented hip is in contrast to recent meta-analyses[12,13] and registry data.[7-9,11,25] Toossi et al,[13] in a meta-analysis including only studies with minimum ten-year follow-up, concluded that the preference for cementless acetabular components was not supported by published literature. The difference in results between cemented and hybrid THA in our series appears to be mainly due to the uncemented acetabular components performing very well, with 95% survival at 18 years. Registry data typically reports all-cause revision which includes reasons that may not be implant or fixation specific such as infection and dislocation. We had low rates of revision for these complications. Classes of implant are reported which may include some implants that are not performing as well as others. The meta-analyses have included papers with short-term follow-up. It is known that there are higher rates of early revision for uncemented components. Cemented hips are less likely to be revised early but start to fail after ten years or more. They have also included older papers using uncemented components that may have had problems with locking mechanisms and polyethylene wear. Unlike most studies, we used a high proportion of monoblock acetabular components (70%) which are showing an advantage in the NZJR.[7] We have previously reported 93.4% survival of the Morscher acetabular component at 20 years for all-cause revision and 97.1% survival for aseptic loosening, wear, or osteolysis despite using conventional polyethylene.[15] The RM implant also has excellent long-term results.[16] Of the modular acetabular components we used, the Fitmore/Fitek

(Zimmer) use the same mesh for fixation as the Morscher implant, and the Trident (Stryker, Mahwah, New Jersey, USA), and Reflection (Smith & Nephew, Memphis, Tennessee, USA) acetabular component have not been reported in the literature as having major faults in design.

Previous papers using competing risk have noted that it tends to give a higher survival figure than the more widely used Kaplan-Meier analysis.[26-28] It recognizes that death or revision for another reason completely preclude revision or cause-specific revision respectively and so does not treat these events as censoring (denoting that the event of interest has not yet happened but eventually will happen) as would be the case under Cox's proportional hazards and similar models. Therefore the revision-free survival in the cemented group was 88% compared with 82% from Kaplan-Meier analysis due to 42% dying in this group. The difference seen in the hybrid group between the methods was minimal as only 17% of patients had died. The hazard ratios would have been over 20% higher in favour of hybrid fixation in this study had we not allowed for competing risk. Therefore we believe that the use of competing risk analysis gives a more realistic but conservative estimate of the difference between the two groups.

The strengths of this paper are the size of the series and length of follow-up. The public hospital policy of using cemented components in most patients, while there was unrestricted choice in the private hospital, has given an opportunity to compare the cemented and hybrid cohorts. The Exeter stem is known to perform well and good numbers had been used in combination with both cemented and cementless cups. The surgical procedure was relatively well standardized with a 28 mm head on conventional polyethylene used in most cases. The surgeons were experienced and trained in both cemented and hybrid procedures and most operated in both hospitals. We saw low revision rates for infection, dislocation, and periprosthetic fracture. Therefore, survivorship mainly reflects acetabular fixation and wear related issues, which are factors that can be influenced by implant choice.

A limitation of the study is that is observational rather than randomized and we used a number of different acetabular components. The public hospital policy and resultant disparity in use of implants is a potential source of bias. In the public hospital, trainees under direct supervision performed over 40% of the cemented hips but very few of the hybrids. However, this did not appear to have an impact on the results. The patients were not equally matched, with the hybrid group significantly younger and having a higher proportion of males. Registry data, however, suggests that this would be expected to lead to poorer survivorship rather than the improved survivorship seen.[7] Highly cross-linked polyethylene was used in a small proportion of the hybrid group but this was adjusted for in our model. We have used revision as the endpoint and clinical or radiological failures are not included. However we do not believe that this will significantly alter the findings. While there may be silent wear and osteolysis in the hybrid group there are also likely to be radiolucent lines in a significant proportion of cemented acetabular components.[6] It is not clear how generalizable these results are to other centres and modern practice. The most commonly used uncemented acetabular implant in this series, the monoblock Morscher design, is no longer available despite excellent long-term results.[15] Conventional polyethylene was used in almost all hips with 28 mm modular heads. Despite this excellent long-term survival was found especially in the hybrid group.

In conclusion, this study supports the use of uncemented acetabular fixation over cemented when used in combination with the Exeter component at all ages. There is improved survivorship for all-cause revision in patients less than 70 years of age, predominantly due to the high rate of loosening of cemented acetabular components. Hybrid THA has lower rates of revision for loosening, wear, and osteolysis at all ages. These results provide some evidence to justify the increasing use of uncemented acetabular components that has been seen in the last 20 years.

Take home message

- Cemented components have a higher loosening and revision rate than uncemented components when used with the Exeter stem at long-term follow-up.
- Hybrid fixation has excellent long-term survival.
- This study supports the trend away from cemented acetabular components.

Animation

An animation is available alongside the online version of this article.

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AR. Gray: Performed the statistical analyses for the survival models, Reviewed the manuscript

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■ CASE REPORTS

Bilateral, uncemented total hip arthroplasty in osteopetrosis

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Bilateral, uncemented hip replacements were performed on a 45-year-old woman with autosomal dominant osteopetrosis. The hips showed degenerative changes and protrusio acetabuli. Difficulties were encountered especially during preparation of the femoral canal. At ten-year follow-up she has an excellent clinical and radiological result with no sign of osteolysis. Uncemented hip replacement, while technically demanding, can be successful in the intermediate term for patients with this condition.

Osteopetrosis or Marble Bone disease is an uncommon condition. The sex-linked recessive form is associated with childhood problems and early death. However, the autosomal dominant form is compatible with a normal life span, and as many as 40% of patients may remain asymptomatic.[1,2] Bollerslev and Mosekilde[1] described two forms of autosomal dominant osteopetrosis (ADO). In Type 1, there is increased thickness of the cranial vault, diffuse osteosclerosis of the lumbar spine and pelvis and symmetrical, long-bone involvement. Type 2 shows more basal skull involvement, a 'rugger jersey' spine and 'endobones' within the pelvis. Type 2 patients are more prone to fractures which are difficult to treat.

Degenerative changes may occur in the hip and knee after the fifth decade, sometimes in the presence of deformity, especially coxa vara,[3,4] and sometimes without.[5-10] There have been several early reports of hip arthroplasty for this condition, but we believe that this is the first report of an uncemented total hip arthroplasty (THA) in osteopetrosis.

Case report

In 1992, a 45-year-old female laundry worker presented with a seven-year history of low back and bilateral hip pain with stiffness. She had severe pain at rest and at night, a walking duration of 10 minutes without aids and was unable to put on shoes or socks. She had 80° of hip flexion on both sides with no rotation, adduction or abduction. Her Harris Hip score (HHS) was 39 (pain 10, function 21).

Radiographs showed bilateral protrusio acetabuli and degenerative changes of the hips (Fig. 1). The long bones were uniformly dense with very narrow medullary canals. The lumbar vertebrae were also dense with degenerative changes present. The radiograph of the skull showed thickening of the cranial vault. These changes were consistent with ADO Type 1.

She underwent bilateral, staged THA three months apart. The femoral neck was very hard to cut and the cut surface showed no obvious medullary canal. A 52 mm CLS Expansion cup (Centerpulse Orthopedics, Munsinger, Switzerland) was inserted into the acetabulum after routine power reaming. Drills were used to create a medullary canal breaking two drill bits in the process. The femur was then sequentially reamed with power reamers and hand-held conical reamers to allow the insertion of a 14 mm Wagner cone prosthesis (Centerpulse Orthopedics) which has a rough-blasted, titanium, conical stem with fins. There were no post-operative complications.

Histopathological examination of the femoral head revealed a thickened cortex and variably thickened bony trabeculae. In some areas, the trabeculae were markedly widened with both a woven and lamellar pattern, and islands of pale staining, alcian-blue positive, myxoid material (Fig. 2) which may represent the remnant cartilaginous bridges which are typical of osteopetrosis. Delicately vascularised adipose tissue replaced haemopoietic marrow. Osteoclasts were seen in neither histological nor electronmicrographic sections. These histological features indicate abnormal bone remodelling and, when taken in conjunction with the clinical and radiological findings, are consistent with ADO Type 1 as described by Bollerslev and Mosekilde.[1] The articular surface was eburnated and any remaining articular cartilage was fibrillated, as is seen in osteoarthritis.

At two-year follow-up, tomography (Fig. 3) suggested bone ongrowth with trabecular lines seen running from the threads of the cup. The HHS was 93 (pain 40, function 44). At the latest follow-up (ten years), she continues to have a good result with an HHS of 91 (pain 40, function 42), an Oxford-12 item hip score of 25, and a WOMAC score of 60 (pain 12, motion 5, function 43). Her short-form (SF)-12 physical score is 41.41 and her mental score is 42.20. She has residual discomfort from her lumbar spine but is satisfied with the results of her hip arthroplasties. The latest radiograph (Fig. 4)

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Fig. 1a

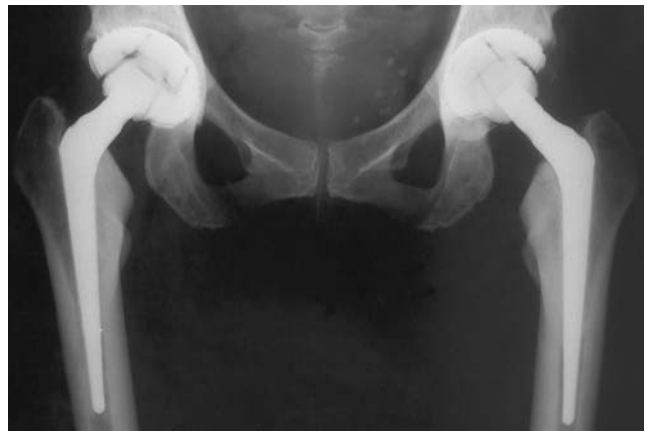

Fig. 1b

Fig. 1a – An anteroposterior (AP) radiograph of the pelvis showing dense sclerotic bone of osteopetrosis, degenerative changes in both hips and protrusio acetabuli. Fig. 1b – An AP radiograph of the pelvis, two years after surgery.

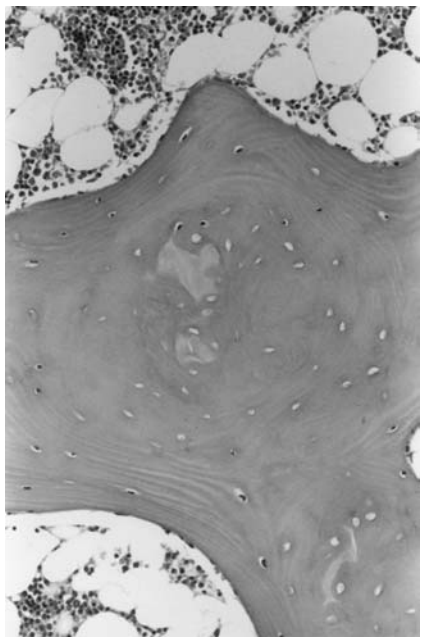

Fig. 2

Photomicrograph of the femoral head showing markedly widened bony trabeculae with central islands of pale staining myxoid material (haematoxylin and eosin x 78).

Fig. 3

A tomogram of the right hip at two years showing bone trabeculae running from the titanium threads of the Expansion cup.

shows apparently solid fixation of the components with no osteolysis. There has been minimal remodelling of the canal created distal to the femoral stem.

Discussion

The gene disorders in osteopetrosis result in decreased osteoclastic resorption of bone. Where present, osteoclasts lack the usual ruffled border that is important in bone resorption. The abnormal osteoclastic function results in very hard bone with thickened trabeculae. Coxa vara is a well-recognised complication of osteopetrosis with most cases developing during childhood,[2,10] sometimes after fracture of the femoral neck or subtrochanteric region.[3]

Degenerative changes often occur after the age of 40[5-10] in the absence of deformity. Articular cartilage is not affected by the disorder, and it has therefore been suggested that the degeneration occurs because of the hard unyielding subchondral bone.[6,8] Protrusio has not been reported previously. We speculate that it may have occurred because the acetabular bone was relatively less hard than the femoral head.

Fig. 4

A radiograph 10 years after surgery showing no osteolytes and minimal remodelling of the medullary canal distal to the femoral stem.

There are several case reports of hip and knee arthroplasty with follow-up ranging from six months to six years.[3-10] Technical difficulty has been experienced especially on the femoral side. Drills and high-speed burrs, guided by fluoroscopy, have been used to help create a medullary canal. Previously, cemented components have been used. Matsuno and Katayama[4] used a press-fit acetabular component with screw fixation, since it would be difficult to obtain good quality bone-cement interface, but considered that to use a cementless femoral component risked fracturing the shaft. We found that the use of the Expansion cup allowed more controlled insertion and may reduce the risk of acetabular fracture. The shape and small size of the Wagner cone prosthesis allowed power reaming of the femur and avoided downsizing the component to allow a cement mantle. Poor cement-bone penetration would be expected to occur in the dense sclerotic bone.

Fracture healing occurs slowly in osteopetrosis and slow bony ongrowth to the titanium prosthesis would be expected, which appears to have occurred in our case. Serial radiographs over a period of 10 years show no progressive osteolysis despite a high level of activity. There has been minimal remodelling of the femur where the medullary canal was reamed out. The osteoclast has a central role in osteolysis due to particulate debris and patients with osteopetrosis may have an inhibited process of osteolysis.

In summary, we believe that this is the first reported case of fully cementless THA in osteopetrosis. At intermediate follow-up of ten years, the clinical and radiological results are good. Protrusio acetabuli has not previously been described in this condition.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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Case report

Polyethylene liner dissociation with the Pinnacle acetabular component: should we be concerned?

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ABSTRACT

Between 2007 and 2018, 535 total hip arthroplasties using the uncemented Pinnacle acetabular component (DePuy Synthes, Warsaw, IN) and polyethylene liner were implanted in our unit. Of these, 6 patients presented acutely with liner polyethylene dissociation, giving a rate of liner dissociation of 1.11%. All dissociations were atraumatic. Failure occurred at mean 37 months (range 4.5 to 130 months). Radiologically, all acetabular components were within safe zone of abduction and mean anteversion was 10 degrees (range 2-20). In one case, there was posterior impingement against the femoral neck due to femoral malalignment. All patients underwent head and liner exchange with no repeat failures. Despite excellent long-term results, the frequency of dissociated polyethylene liners is a cause of concern with the Pinnacle acetabular component.

Introduction

Over recent years, there has been a move toward uncemented acetabular components. [1,2]. The majority are modular which allows for flexibility and adaptability in total hip replacements. It gives options for screw fixation, various liner configurations, and may allow straightforward revision for dissociation or liner wear.

Although it has advantages, modularity also has potential problems. One issue is dissociation of the liner from the metal shell. It was mostly reported in first-generation uncemented components such as the Harris-Galante 1 (Zimmer Biomet, Warsaw, IN) [3,4]. Early locking mechanisms and incongruity between the liner and shell were thought to be the main causes of failure. Improvements in component design have reduced the incidence of this problem such that it is now rarely seen in contemporary designs.

Current modern acetabular designs have recessed liners to reduce the risk of rim fractures and improved locking mechanisms at the perimeter [5]. The Pinnacle acetabular system (Depuy, Warsaw, IN) was introduced in 2003. It is now one of the most commonly used acetabular components [1,2]. It uses a taperloc locking mechanism with 6 antirotation devices or tabs at the periphery which provide rotational stability but do not affect pull-out strength. This provides better conformity but reduced pull-out strength in comparison with the DuraLoc system (Depuy, Warsaw, IN) which used a locking ring. [6] Nonetheless, clinical results from registries and prospective studies with the Pinnacle system have been excellent and a 97% to 94% survival is reported at 5 and 10 years, respectively, by Kindsfater et al in a multicentre study [7]. However, there have been an increasing number of reports of polyethylene liner dissociation from several countries [8-12]. Dissociation can be early or late and have usually been with no trauma. This problem has been rarely reported with other contemporary modular acetabular systems [11].

We have used the Pinnacle acetabular component since 2007 in our unit and have seen 6 polyethylene liner dissociations. We are aware of reports from other centers in our country [12]. The purpose of this study is to report a further series of liner dissociations, calculate the incidence in our center, and to identify possible reasons for this uncommon complication.

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to https://doi.org/10.1016/j.artd.2019.12.001.

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Case series

Departmental audit data identified 6 patients who underwent revision for liner dissociation of a Pinnacle acetabular component in our unit. Our local database was cross-referenced to the New Zealand National Joint Register (NZNJR) to identify all patients who had undergone total hip arthroplasty (THA) with a Pinnacle acetabular component and a polyethylene liner in our unit since its introduction. The NZNJR captures details of all arthroplasties performed in our country and has 98% compliance. It also includes details of revisions of registered arthroplasties performed at any center in the country [1]. No revisions of this cohort were recorded from other centers. The operative records and radiographs of all patients who had been revised were checked to confirm the diagnosis of liner dissociation and ensure that the reason for revision had not been miscoded.

Details of all patients identified with liner dissociation were recorded including their history since the start of new symptoms. Index THA operation notes were reviewed for details of the procedure and components used. Postoperative anteroposterior and lateral radiographs were reviewed to assess acetabular cup abduction and anteversion. Anteversion was measured on a cross-table lateral radiograph [13]. The operative findings at revision surgery were recorded.

Between 2007 and 2018, approximately 5200 primary THAs were performed in our unit; of these, 535 utilized a Pinnacle acetabular component with a polyethylene liner. Marathon highly cross-linked polyethylene was used in all cases. All procedures were either carried out by a fellowship trained arthroplasty surgeon or a senior trainee supervised by a consultant. 277 (52%) were used in combination with an uncemented femoral component and 269 (48%) with a cemented femoral component (hybrid). A metal head was used in 226 (42%) and a ceramic head in 309 (58%). A 32 mm head was used in 293 (55%) and a 28 mm head in 234 (44%) with 8 cases (1%) using a 36 mm head.

During this period, 6 patients presented to us with acute liner dissociation. Details are summarized in Table 1. Four had their index THA for end-stage osteoarthritis and two were for acute fracture neck of femur. Five were performed using the direct lateral approach and one via a posterior approach. The mean time to presentation with dissociation was 37 months (range 4.5 months to 10.8 years). There were no recorded concerns about the liner seating during the index THA. Three patients were asymptomatic till the failure of liner occurred. Two had a subjective feeling of subluxation in the months before presentation and one had new onset pain a few weeks before actual dissociation. Plain radiography was diagnostic with asymmetry of the femoral head within the acetabular component (Fig. 1). The mean abduction angle of the acetabular cup was 39 degrees (range 35 to 42). The mean anteversion was 10 degrees (range 2 to 24).

At the revision, all acetabular components were well fixed and the liner clearly loose. Typically, the superior 3 tabs had sheared off (Fig. 2). In 5 hips, acetabular and femoral components were well positioned. In one hip, there was posterior impingement of the femoral neck on the polyethylene secondary to excessive anteversion of the femoral component. The acetabular shell was retained, a new liner inserted, and the femoral component revised. One acetabular component had signs of pitting due to the metal head articulating against it. It was retained because of the age of the patient who died 3 years later due to an unrelated medical illness. All acetabular components were retained and a new polyethylene liner inserted after checking the locking mechanism integrity in 5 cups. In one patient, a new liner was cemented into the metal shell because of concerns about the competency of locking mechanism. The femoral head was exchanged in all cases. No further complications have been recorded in revised patients at their most recent follow-up.

Discussion

The Pinnacle acetabular system has been in use since 2003 with excellent long-term survivorship. It is currently the most widely implanted acetabular system in New Zealand [1]. Mid-term and registry reports are encouraging with survivorship for all-cause revision of 97.6% at 5 years [14] and 95% at 10 years [7]. Despite this, there have been increasing numbers of reports of liner dissociation of the Pinnacle system [8,10,11].

Liner dissociation was a problem with early designs of modular uncemented acetabular systems especially the Harris-Galante [3]. A more robust locking ring was used in second-generation designs

Table 1
Cases with Pinnacle liner dissociations.

No	Age	Gender	Indication	Time to presentation (months)	Implants	Approach	Cup Abd.	Cup Anteversion	Revision type	Intra-op findings
1	69	M	OA	12.3	Pinnacle/Corail (KHO) 56/28 mm MOP No screws	Lateral	38	10	Change of liner	Well-fixed cup. Acceptable alignment and no impingement
2	87	M	NOF #	13.1	Pinnacle/Corail (KHO) 56/32 mm COP No screws	Posterior	35	24	Change of liner	Pitted but well-fixed cup. Accepted due to age and comorbidities. (RIP 3 years post revision due medical illness)
3	58	M	OA	4.43	Pinnacle/Corail (KLA) 54/28 mm COP No screws	lateral	40	4	Change of liner	Well-fixed cup. Acceptable alignment and no impingement
4	64	M	OA	58.3	Pinnacle/Corail (KHO) 56/28 mm COP No screws	lateral	41	2	Cemented liner in existing cup	Well-fixed cup. Impingement against femoral neck in external rotation due to stem anteversion. Subsequently revised to tapered fluted modular stem with less anteversion.
5	70	M	OA	130	Pinnacle/Corail (KHO) 58/28 mm COP No screws	Lateral	37	10	Change of liner	Well-fixed cup in acceptable alignment and no impingement
6	61	F	NOF #	5	Pinnacle/Exeter V40 50/28 mm COP No screws	Lateral	42	11	Change of liner	Well-fixed cup. Acceptable alignment and no impingement

OA, osteoarthritis; NOF #, neck of femur fracture; KHO, high offset Corail stem; COP, ceramic on polyethylene bearing; MOP, metal on polyethylene bearing.

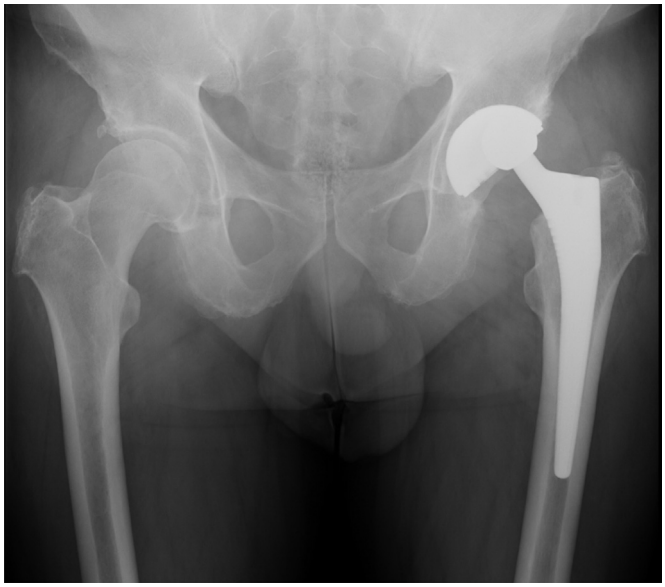

Figure 1. Internal subluxation of femoral head within the socket.

such as the Duraloc [6]. A taperloc mechanism was introduced in the Pinnacle component to accept both polyethylene and ceramic or metal bearings with 6 tabs to resist rotation. The liner was also changed from conventional polyethylene to a highly cross-linked polyethylene (Marathon) irradiated to 50 kGys, which improved wear characteristics but at the expense of mechanical strength [15,16]. The effect these changes has is a reduced pull-out strength of the liner [17].

It is not clear what the incidence of liner dissociation is for the Pinnacle system. The rate of liner dissociation in our unit is 1.11%. We are confident of the rate as we were able to check operative details of all revisions of the cohort recorded in the NZNJR. In the largest series of liner dissociation, Yun et al reported on 23 cases of liner dissociations in 2646 THAs from 3 arthroplasty centers in the United States (incidence: 0.3%-0.83%) [8]. Singleton reported 6 liner dissociations in 253 (2.4%) THAs [12]. By contrast, Napier et al reported only 8 polyethylene liner dissociations from 4751 Pinnacle acetabular components from a single center (0.17%) [11].

Increased rates of dissociation of liners from the Pinnacle component have not been identified from registry data. Jameson reported 10 cases of liner dissociations in 35,386 Corail Pinnacle THAs from the National joint registry of England and Wales [14]. However, only 13,923 of these used polyethylene liners giving an incidence of 0.07% if all dissociations were of polyethylene liners. Registry data in Australia and New Zealand does not have a specific field for liner dissociation as a cause. We found that the reason for revision may be entered as dislocation, acetabular loosening, or "other cause". Therefore, this particular problem may be underestimated in registries. The Pinnacle cup is performing very well in other respects. The revision for dissociation rate is low compared with other reasons for early revision such as dislocation and infection so it may go undetected in registry data unless specifically searched for.

It is not clear why there are multiple reports of dissociation with the Pinnacle acetabular component and not with other contemporary systems. This suggests a problem with the locking mechanism which may be less forgiving than other systems. The Pinnacle system allows for the use of neutral, lipped, lateralized, and a 10° face changing liner option. Liner dissociation may be more common in neutral and face changing liners compared with lipped ones. In Yun's

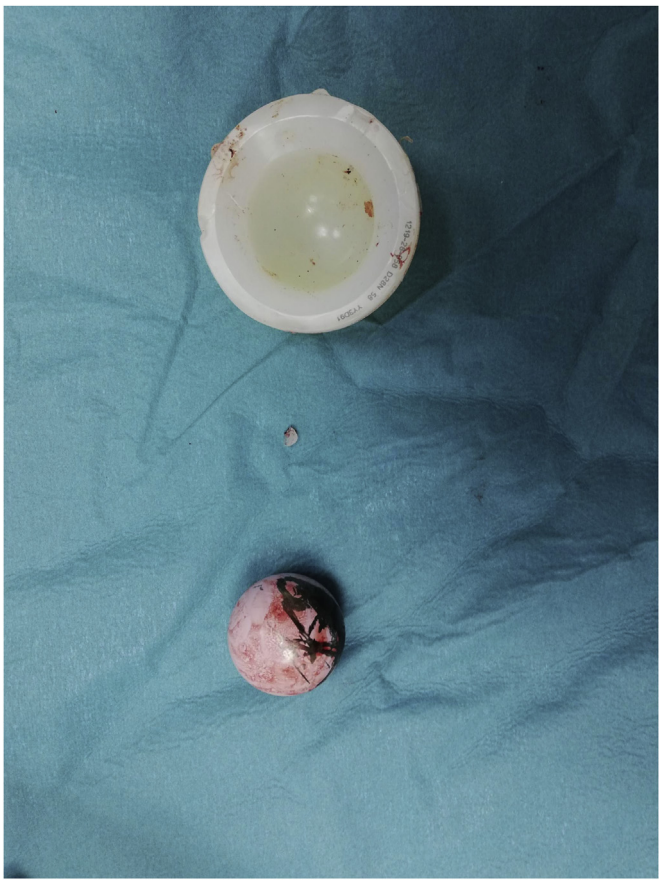

Figure 2. Retrieved polyethylene insert and head showing fractured tabs and deformed shape.

series, 13 of 23 liners were neutral, 9 were +4 10 degrees lateralized with only one lipped liner [8]. A neutral liner was used in 5 of 6 of our cases, and in all cases from Singleton and Kagan [10,12]. This is a little surprising as an elevated lip may be more likely to lead to eccentric loading, rim fractures, or impingement than a neutral liner. However, the polyethylene liner in the Pinnacle system sits slightly proud of the metal rim. Therefore, if the neck impinges on the cup, it will contact the polyethylene first even in neutral liners. Prominence of screw heads could potentially contribute to incorrect seating of the liner. However, screws were not used in any of our cases and do not appear to be associated with dissociation in other series.

There has been little discussion on surgical approach as a factor influencing dissociation. A lateral approach was used in 5 of 6 cases in our series. Singleton reported all their dissociations occurred with the lateral approach and none with a posterior approach [12]. Kagan used a direct anterior approach in all their cases [10]. By contrast, there was a very low incidence of dissociation in Napier's series using neutral liners and a posterior approach [11]. It is not clear why approach should have an effect. With a lateral approach, it is our practice to place the acetabular component in less anteversion and to use a neutral liner rather than a lipped liner which we prefer with a posterior approach. Visualization of the acetabulum can be more difficult with a lateral approach which could lead to problems with soft tissue interposition. A good view of the acetabulum can and should be obtained with any approach and it is important to clear any soft tissue to ensure concentric seating of the liner before final impaction.

In our series and most other reports, most THAs were reported to be functioning well before dissociation. This suggests that the liner was correctly seated at the time of surgery. Early dissociations

occurring within the first 2 years have been reported to be associated with acetabular malposition such as a high abduction angle or over/under anteversion [9,18,19]. However, in our series, all were within the safe zones of abduction described by Lewinnek et al [20]. In only one case was there posterior impingement, which was thought to be due to femoral component malposition. In Napiers's series, 2 of 4 cases with overabducted acetabular components had a recurrent liner dissociation [11]. They thus recommend revision of the acetabular component in such cases. Late dissociations at 5 to 10 years in well-positioned THAs strongly suggest that there is a problem with the Pinnacle locking mechanism.

There may be further patients who have some instability of the liner but do not develop frank dissociation. Three patients in our series had some prodromal symptoms of pain or subluxation in the months preceding the actual dissociation. This diagnosis needs to be considered. However, radiological diagnosis is difficult in such patients. One had a radiograph taken due to a subjective feeling of subluxation which showed a congruent hip joint. Computed tomogram (CT) is a well-recognized tool in assessment of polyethylene wear and component alignment in hip arthroplasty [21]. We are unaware of any cases where a CT has been used to detect polyethylene dissociation; however, a thin-slice metal suppression CT may detect subtle changes not evident on plain radiographs.

Treatment of liner dissociations should be individualized. In cases where the acetabular component is well aligned with an intact locking mechanism, a head and liner exchange may be appropriate. We have not observed recurrent liner dissociation in our series. If impingement or malalignment is present, a revision of either acetabular or femoral component should be considered to reduce the risk of redissociation. Cementing a liner into a well-fixed acetabular component is an option if there are concerns about the integrity of the locking mechanism.

Summary

Liner dissociation is an important complication seen with the Pinnacle acetabular component. Although some cases could be attributable to technical issues such as incomplete seating, impingement or malalignment, the increasing numbers reported with this device, especially at long-term follow-up, coupled with the lack of reported dissociations with other contemporary modular acetabular components suggests that there are problems with the locking mechanism. Comparative studies of similar acetabular components and mechanical testing under different loading conditions may help to provide the answers.

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Original research

Acetabular Liner Dissociation: A Comparative Study of Two Contemporary Uncemented Acetabular Components

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ABSTRACT

Background: There are a number of reports of polyethylene liner dissociation of third-generation modular acetabular components. This study compares our experience with 2 contemporary systems to determine whether this is an implant- or class-specific problem.
Methods: This is a single-center retrospective study of 961 primary total hip arthroplasties using 2 third-generation modular cementless acetabular shells: Pinnacle (535) and R3 (426) with a polyethylene liner. Details of all revisions were obtained from local databases and the New Zealand Joint Registry. Kaplan-Meier survival curves were calculated for all-cause revision, acetabular reoperation (including liner exchange), and liner dissociation.
Results: There were 17 revisions in group 1 (Pinnacle; DePuy Synthes): 17 for recurrent dislocation, 6 for liner dissociations (1.12%), 3 for femoral loosening, and one for deep infection. In group 2 (R3; Smith and Nephew), there were 4 revision procedures: one for infection, 2 for dislocation, and one femoral revision for periprosthetic fracture. There were significantly higher proportions revised in group 1 for all-cause revision, acetabular reoperation, and dissociation ($P = .024$ to 0.038). The 7-year survival for all-cause revision was 96.1% for Pinnacle and 99.0% for R3 ($P = .022$), and that in the acetabular reoperation group was 96.9% for Pinnacle and 99.3% for R3 ($P = .035$).
Conclusions: There was a higher revision rate for the Pinnacle acetabular component than for the R3 at 7 years. This was mainly due to polyethylene liner dissociation that can occur early or late. It appears to be a problem specific to the Pinnacle cup design rather than a feature of similar third-generation acetabular components.

Introduction

Uncemented acetabular components are widely used in modern total hip arthroplasty (THA) [1-3]. Most are modular, which has a number of advantages including the ability to use supplementary screw fixation, and allow ceramic and polyethylene bearings, different head sizes, and the use of lipped and face-changing liners. A problem with modularity is polyethylene liner dissociation, which was a complication of older uncemented acetabular components [4,5]. Improvements in locking mechanisms had almost eliminated this problem. However, the problem has reemerged with the development of third-generation acetabular components [6-11]. These cups have been designed to accept multiple liner options and use a taper lock mechanism with no locking ring. The polyethylene liner is recessed within the shell to reduce the risk of rim fractures.

In recent years, there has been a shift away from cemented cups toward modular uncemented acetabular components in our unit. The most frequently used are the Pinnacle cup (DePuy Synthes, Warsaw, IN) and the R3 cup (Smith and Nephew, Memphis, TN), which were introduced around the same time and have a similar design. We have previously reported a series of liner dissociations with the Pinnacle cup from our unit and concluded that although some cases could be attributable to technical issues such as incomplete seating, impingement, and malalignment, the increasing numbers reported, including late dissociations, and the lack of reports with other systems suggested a problem with the locking mechanism [11]. The rate of liner dissociation is reported to

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be very low [6,7,12], but it may be underreported particularly in registry studies [6]. It is not clear whether this is an implant-specific issue or a feature of other third-generation designs.

The purpose of this study was to compare our experience with 2 similar contemporary third-generation modular acetabular components used over the same time period from the same center. The primary outcome was revision for liner dissociation. Secondary outcomes were all-cause revision and acetabular reoperation. The null hypothesis was that there is no difference between the 2 systems.

Material and methods

This is a retrospective comparative study comparing all primary THAs performed at either our public or private hospital using the Pinnacle Cup (group 1) and the R3 cup (group 2) between August 2007 and August 2019, with minimum 1-year follow-up. All patients undergoing primary THA using these cups and any subsequent revision were identified from our local audit database cross-referenced to the New Zealand Joint Registry (NZJR) [1]. Only patients with a polyethylene liner were included. All indications for surgery including acute fracture were included. All procedures were performed by or under the direct supervision of 10 consultant surgeons experienced in hip arthroplasty. Approach and implant choice were at the surgeon's discretion. All 10 surgeons used the Pinnacle cup, with 6 also using the R3 cup.

Patient demographics and operative variables are shown in Table 1. There were 535 hips in the Pinnacle group and 426 in the R3 group. There was a higher proportion of females in the Pinnacle group. The Pinnacle group was significantly more likely to have been performed via a lateral approach using an uncemented stem, a neutral liner, and a 28-mm metal head than the R3 group. The R3 group had significantly longer mean follow-up. The NZJR and our audit database were used to identify any revision procedure on these patients. Chart and radiographic reviews were used to determine the causes of revision including specifically those due to liner dissociation.

Table 1
Comparison of baseline demographics and operative variables for Group 1 (Pinnacle) and Group 2 (R3).

Patient demographics and operative details	Group 1 Pinnacle	Group 2 R3	*P* value
Number	535	426	
Male	249 (47%)	229 (54%)	.03
Female	286 (53%)	197 (46%)	
Age	66.3 (41-95)	63.1 (33-81)	<.001
Deaths	34 (6.4%)	23 (5.4%)	.58
Femoral component			
Exeter (Stryker)	258 (48%)	275 (64%)	<.001
CORAIL (DePuy Synthes)	274 (51%)	5 (1%)	
Polar stem (Smith and Nephew)		110 (26%)	
Spectron (Smith and Nephew)		19 (5%)	
Synergy (Smith and Nephew)		16 (4%)	
Others	3 (1%)	1	
Head material			
Ceramic	311 (58%)	289 (68%)	.002
Metal	224 (42%)	114 (27%)	<.001
Oxinium		23 (5%)	<.001
Head size			
28 mm	234 (44%)	99 (23%)	<.001
32 mm	293 (55%)	323 (76%)	<.001
36 mm	8 (1%)	4 (1%)	.14
Approach			
Posterior	337 (63%)	397 (93%)	<.001
Lateral	198 (37%)	29 (7%)	<.001
Cup			
No hole	303 (57%)	314 (74%)	<.001
Three-hole	224 (42%)	111 (26%)	<.001
Multihole	6 (1%)	1 (0.2%)	
Mean follow-up/years (SD) range	4.1 (3.1) (1-11.9 years)	5.0 (2.3) (1-10.3 years)	*P* < .001

SD, standard deviation.

Design and surgical technique

The Pinnacle shell is made from titanium and has no hole, cluster (3-hole), and multihole options. It has a short taper locking system that allows it to take ceramic and metal inserts. Marathon polyethylene liners were used in all cases in this study. These are gamma-irradiated with 5 Mrad in gas and are fully annealed.

The R3 shell is also made of titanium and has a hydroxyapatite coat. There are no-hole and 3-hole options. The highly cross-linked polyethylene (XLPE) is gamma-irradiated in gas with 10 Mrad and fully annealed. There are 20-degree lipped or neutral options. Our preference is to use a no-hole shell with a central hole cover unless supplementary screw fixation is felt necessary. Initially, we found it difficult to seat the liner within the shell because of blood interfering with the highly conforming geometry. This was less of a problem with the cups with holes for screw fixation. We now routinely keep our R3 polyethylene liners in the freezer at −18°C. The small degree of shrinkage of the liner allows egress of any blood or fluid and allows secure locking.

Statistical analysis

A paired t-test was used to compare continuous variable and Fisher's exact test for categorical variables. Kaplan-Meier survival curves with 95% confidence intervals were drawn for all-cause revision, acetabular reoperation (including liner exchange), and liner dissociation. An a priori power study calculation assumed there were no further cases of liner dissociation compared with the 6 cases we have reported previously. We estimated that we needed 400 THAs using the R3 cup to show a statistically significant difference between the groups (Fisher's exact test, $P < .05$).

Results

Group 1 (Pinnacle)

There were a total of 17 revisions. There were 6 liner dissociations (1.12%). All had previously been identified and detailed in our case series [11]. The mean time to presentation with dissociation was 37 months (range: 4.5 months to 10.8 years), with 4 of 6 presenting within 13 months of the initial procedure. The remaining 2 cases were at almost 5 years and 10.8 years, respectively. Five were male, and 5 underwent a lateral approach. Screws had not been used in any of the shells. A 32-mm head was used in one case and 28-mm heads in the remaining 5 patients. A neutral liner was used in all cases. The primary operations had been performed by or under the supervision of 4 different surgeons over a 10-year period. At revision, the liners were all grossly loose and typically the 3 superior antirotation tabs had sheared off. All shells were well positioned and well fixed, and none were revised. One femoral stem was impinging posteriorly because of excessive femoral anteversion and was revised. A new liner was inserted in 5 cases, and a liner was cemented into the shell in one case because of concerns about the locking mechanism. There have been no cases of repeat dissociation or failure (Table 2).

Seven revisions were for recurrent dislocation (6) or subjective instability (1). All shells were well fixed at the time of revision. One patient with deep infection underwent debridement with liner and head exchange. There were 3 revisions for loosening of uncemented stems.

Table 2
Details of patients who had an acetabular liner dissociation.

Age	Sex	Indication for primary THA	Time to presentation with dissociation (months)	Acetabular details (shell, liner)	Femoral component, head	Approach	Cup abduction angle	Cup anteversion angle	Revision procedure
69	M	OA	12.3	Pinnacle 56/28 mm Neutral No screws	CORAIL (KHO) 28 mm metal	Lateral	38	10	Change of liner
87	M	# NOF	13.1	Pinnacle 56/32 mm 10 degree lip No screws	CORAIL (KHO) 32 mm ceramic	Posterior	35	24	Change of liner
58	M	OA	4.43	Pinnacle 54/28 mm Neutral No screws	CORAIL (KLA) 28 mm ceramic	Lateral	40	4	Change of liner
64	M	OA	58.3	Pinnacle 56/28 mm Neutral No screws	CORAIL (KHO) 28 mm ceramic	Lateral	41	2	Cemented liner in the existing cup Stem revised for impingement
70	M	OA	130	Pinnacle 58/28 mm Neutral No screws	CORAIL (KHO) 28 mm ceramic	Lateral	37	10	Change of the liner
61	F	# NOF	5	Pinnacle 50/28mm Neutral No screws	Exeter V40 28 mm ceramic	Lateral	42	11	Change of the liner

OA, osteoarthritis; #NOF, fractured neck of the femur; KHO, high offset; KLA, lateralized.

Group 2 (R3)

There were 4 revision procedures in total. There were no cases of liner dissociation. There were 3 revisions of the liner and head: one for early deep infection and 2 for dislocation at 11 and 18 months, respectively. There was one femoral revision for periprosthetic fracture at 15 months.

There was a significantly higher proportion revised in group 1 for liner dissociation, all-cause revision, and acetabular reoperation (any reason) ($P = .024$ to 0.038, Fisher's exact test) (Table 3).

The revision rate for dislocation (excluding dissociation) was higher in group 1 (1.3%) than in group 2 (0.5%) but did not reach statistical significance (Fisher's exact test, $P = .3$). With a low number of dissociations and dislocations observed and a large number of surgeons, there were no statistically significant differences between surgeons in dissociation or dislocation rates. (Table 4).

Table 3
Comparison of revision and survival rates between group 1 and group 2.

Revision and survivorship details	Group 1 (Pinnacle) N = 535	Group 2 (R3) N = 426	*P* value
All-cause revision	17 (3.2%)	4 (0.9%)	**.024**
Rate/100 ocys (95% CIs)	0.78 (0.46-1.25)	0.19 (0.05-0.48)	
KM survival at 7 years % (95% CIs)	96.1 (94.1-98.2)	99.0 (98.1-100)	**.022**
All acetabular reoperations	14 (2.6%)	3 (0.7%)	**.027**
Rate /100 ocys (95% CIs)	0.64 (0.35-1.10)	0.14 (0.03-0.41)	
KM survival at 7 years % (95% CIs)	96.9 (95.2-98.7)	99.3 (98.5-100%)	**.035**
Acetabular dissociation	6 (1.12%)	0 (0%)	**.038**
Rate /100 ocys (95% CIs)	0.28 (0.10-0.60)	0 (0.00-017)	
KM survival at 7 years % (95% CIs)	98.7 (97.4-100)	100 (100-100)	

Ocys, observed component years; KM, Kaplan-Meier; 95% CIs, 95% confidence intervals.
Bold denotes statistical significance $P < .05$.

Kaplan-Meier survival curves were calculated to 7 years (Figs. 1-3). There was a statistically significant decreased survival in group 1 for all end points. The Kaplan-Meier all-cause survivorship for the Pinnacle cup was 96.1% at 7 years compared with 99.0% for the R3 cup. The survival for any acetabular reoperation at 7 years was 96.9% (Pinnacle) and 99.3% (R3). The hazard ratio was 3.6 for all-cause revision ($P = .022$) and 3.9 for any acetabular reoperation ($P = .035$).

Discussion

We have shown a higher revision rate for the Pinnacle acetabular component than for the R3 cup at short-term follow-up to 7 years. This is primarily due to polyethylene liner dissociation that occurred in 6 of 535 cases (1.1%). There were no cases of liner dissociation in the R3 group, suggesting that the problem is specific to the Pinnacle cup rather than a feature of the third-generation acetabular design. Both cups had excellent survivorship for revision for other reasons.

The Pinnacle cup was launched in 2003 and the R3 shell in 2008. Both are widely used and have excellent registry results [2,3]. In the National Joint Registry for England, Wales, Northern Ireland, and the Isle of Man (NJR), the Pinnacle cup with a ceramic-on-polyethylene bearing has a survivorship of 97.19% at 10 years and a cumulative revision rate of 5.2% at 10 years in combination with the CORAIL stem (DePuy Synthes, Warsaw, IN) [3]. In the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), it has a cumulative revision rate of 6.8% at 10 years in combination with the CORAIL stem. In other reports, it has a survivorship for all-cause revision of 95.2% to 99.2%, acetabular revision of 97.0% to 100% at 10 years [12,13], and a cumulative revision rate of 2.5% at 10 years [14]. Our survival figures of 96.1% all-cause survival and 96.9% for acetabular reoperation are in line with these studies.

In the NJR, the R3 cup has a cumulative all-cause revision rate of 2.0% at 7 years and 2.6% at 10 years. The rate for acetabular revision is 0.9% at 7 years and 1% at 10 years. This excluded metal-on-metal bearings but did include ceramic-on-ceramic bearings [3]. The AOANJRR reports a cumulative all-cause revision rate for the R3 cup of 3.3% for ceramic on XLPE and 4.4% for metal on XLPE at 10 years [2]. Others have reported similar results, but ceramic liners were used in a large proportion of hips [15,16]. Our figures of 99.0% for

Table 4
Number of procedures contributed by each surgeon with numbers of revisions for dissociation and dislocation observed for Pinnacle and R3 acetabular systems.

Surgeon	Pinnacle			R3		
	Number	Dissociation	Dislocation	Number	Dissociation	Dislocation
1	77	1	0	81	0	0
2	17	1	0	111	0	1
3	25	0	0	0	0	0
4	22	0	1	0	0	0
5	42	0	0	200	0	1
6	137	3	2	3	0	0
7	151	0	3	1	0	0
8	39	0	0	0	0	0
9	19	0	0	30	0	0
10	6	1	0	0	0	0
	535	6	6	426	0	2

all-cause revision and 99.3% for acetabular reoperation at 7 years compare favorably with these.

There have been multiple case reports and series of dissociations with the Pinnacle cup [6-11,17]. These can be early (within 2 years) or late (2 to 10 years) [10,11]. The rate of liner dissociation with the Pinnacle system is reported to be very low at between 0.17% and 0.8%, but it may be under-reported particularly in registry studies [6,7]. Jameson et al reported only 10 cases of liner dissociations in 13,923 (0.07%) hip arthroplasties from the NJR [18].

We are aware of only one case report with the R3 cup that occurred after a fall in a 56-year-old man 5 years after a complex primary hip replacement [19]. However, a further case report of liner dissociation leading to catastrophic failure of an oxinium head appears to be an R3 shell [20]. There are only 4 revisions reported for liner dissociations in the NJR out of 27,936 cups (0.014%) [3]. However, this includes ceramic and metal liners. The AOANJRR reports 3 revisions for acetabular liner breakage with the R3 from 35,963 hips (0.008%) but does not have a specific field for liner dissociation [2].

Most surgeons and company representatives we have spoken to have suggested that incorrect seating of the polyethylene liner is the reason for the dissociations seen. Although the antirotation tabs sit flush within the shell, the liner is approximately 1 mm proud. This makes it harder to assess seating circumferentially by the use of a dissector. In our experience, if the R3 shell is incorrectly seated, it does not lock and can be easily flipped out by gentle testing at the notch in the rim. Freezing the liner made it easier to seat if a no-hole R3 shell was used. It was suggested by colleagues in another center and, although this is not included in the surgical technique or reported in the literature, we now do it routinely. However, the absence of reported dissociations with the R3 system suggests that this is not critical. If the liner is incompletely seated in the Pinnacle, the locking mechanism may be strong enough to avoid immediate dissociation but may fail early. However, this is unlikely to explain the late cases that we saw at 5 and 10 years.

The locking mechanism in the Pinnacle cup has a relatively short taper and includes a ridge or barb on the liner that locks into a single groove close to the rim of the shell. There are 6 antirotation tabs that sit flush with the shell and resist rotation but have no effect on pull-out strength. The polyethylene sits approximately 1 mm proud of the surface of the metal shell. In contrast, the R3 cup has a longer taper and double-locking groove at some distance from the rim. There are 12 derotation tabs that fit into reciprocal peripheral recesses as in the Pinnacle cup. The liner and tabs sit flush with the face of the metal shell. In addition, there is a small cut out in the shell that allows for gentle testing of the liner after

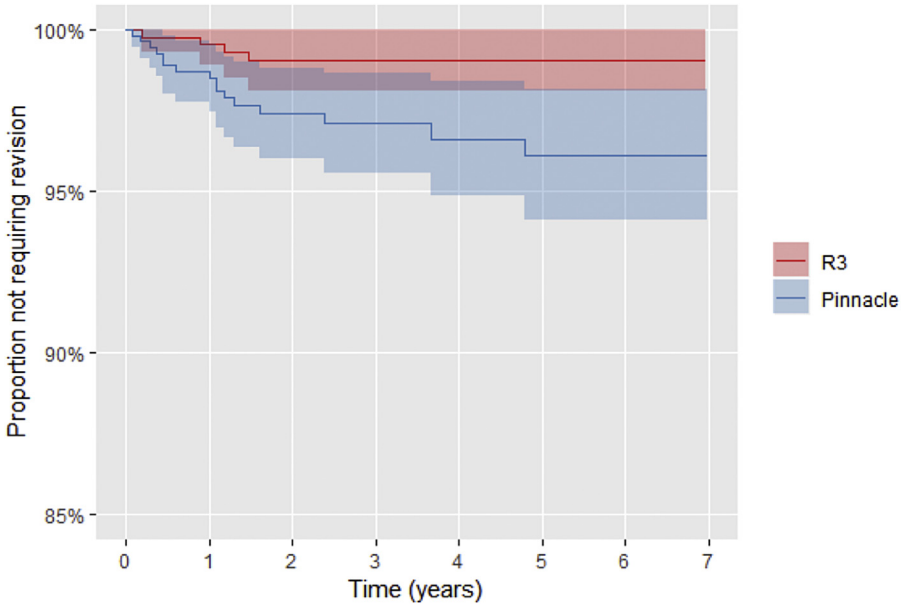

Figure 1. Kaplan-Meier curve showing survival over up to 7 years of follow-up (all-cause revision, censored at the time of death). Percentage survival at final follow-up: R3 = 99.0% (95% CI: 98.1% to 100.0%); Pinnacle = 96.1% (95% CI: 94.1% to 98.2%). Hazard ratio (HR) (Pinnacle) = 3.6 (95% CI: 1.2 to 10.8; $P = .022$). CI, confidence interval.

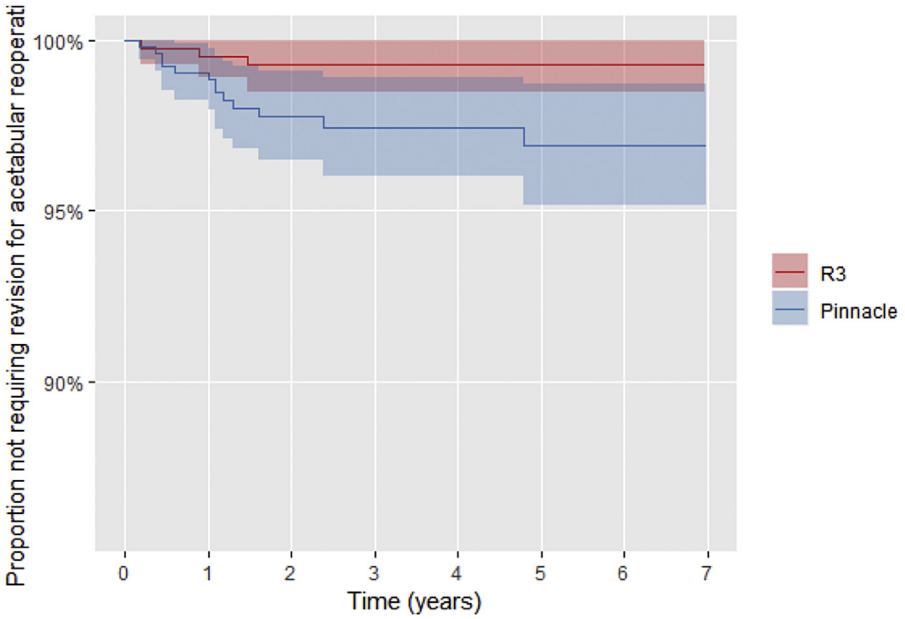

Figure 2. Kaplan-Meier curve showing survival over up to 7 years of follow-up (revision for acetabular reoperation, censored at the time of death or the first revision). Percentage survival at final follow-up: R3 = 99.3% (95% CI: 98.5% to 100.0%); Pinnacle = 96.9% (95% CI: 95.2% to 98.7%). HR (Pinnacle) = 3.9 (95% CI: 1.1 to 13.6; $P = .0353$). CI, confidence interval; HR, hazard ratio.

impaction. It has a push-out strength of 1112 N and resists 40 Nm of torque [21]. The manufacturer claims that it can be reinserted without damaging the locking mechanism.

Other reasons suggested for dissociation may include malposition of the shell, use of face changing liners, impingement, polyethylene fatigue, and rim fracture with thin polyethylene and larger heads [6,7,10,11,22-24]. There were no cases of cup malposition in those patients who dissociated. A higher proportion of 28-mm heads were used in the Pinnacle group, and 28-mm heads were used in 5 of the 6 cases observed. A smaller head size may increase the risk of femoral neck impingement on the polyethylene in the Pinnacle system, whereas the polyethylene is fully recessed in the R3 system. The XLPE in the R3 shell has more cross-linking so would be expected to be weaker and therefore should be more prone to rim failure than the Marathon (DePuy Synthes, Warsaw, IN) polyethylene. We are not aware of any change in the biomechanical properties of the R3 polyethylene liners from storing them at −18°C.

This study reports the experience of well-trained surgeons who are familiar with many uncemented cups. Many used both components in this study. We have not previously identified liner dissociation as a problem in our unit [25]. Therefore, from our results and a review of the literature and registry data, we believe that we are witnessing a problem with the locking mechanism,

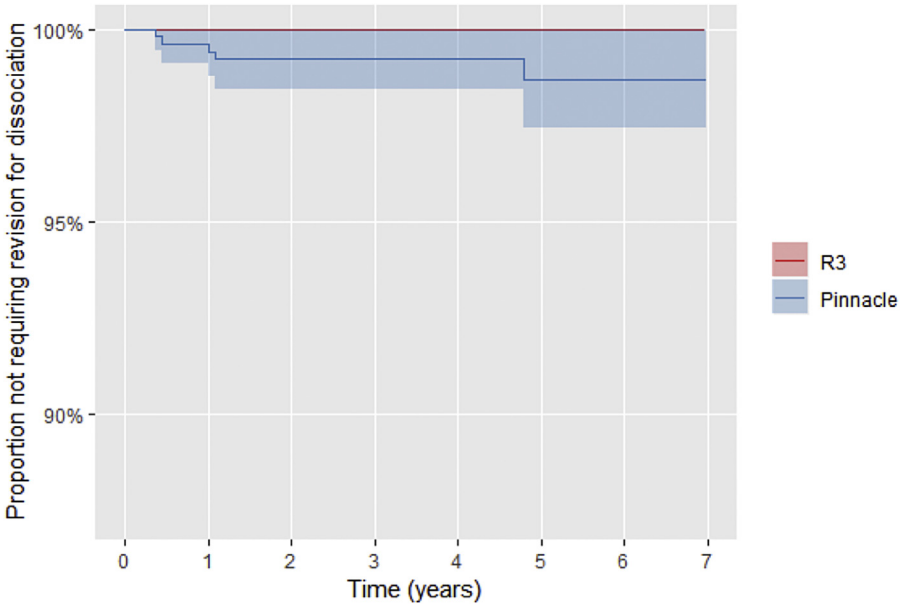

Figure 3. Kaplan-Meier curve showing survival over up to 7 years of follow-up (revision for dissociation, censored at the time of death or the first revision). Percentage survival at final follow-up: R3 = 100.0% (95% CI: 100.0% to 100.0%); Pinnacle = 98.7% (95% CI: 97.4% to 100.0%). CI, confidence interval.

albeit rare, that appears to be specific to the Pinnacle cup rather than the similar third-generation cups.

A limitation of this study is that the groups are not comparable in a number of ways including the approach, gender proportion, femoral component used, and head size. We routinely freeze the liners for the R3 cup to aid insertion but did not do so for the Pinnacle system. We do not have full clinical and radiological follow-up on all cases and did not collect patient-reported outcome scores. However, the end point of dissociation is so dramatic that we believe that revision is an appropriate end point to use for this study. There were more cases in the Pinnacle group with a shorter mean follow-up. Most occurred within the first 13 months, so it is likely that with minimum 1-year follow-up, we have identified early failures. However, as some occurred later than 5 years, the rate may rise with longer follow-up. Owing to the small size of our country and a relatively geographically isolated area, we are confident that the combination of our arthroplasty and audit database, cross-referenced to the NZJR, has identified the correct reason for all the revisions.

Conclusions

We saw a higher revision rate for the Pinnacle acetabular component than for the R3 cup at 7 years. This is mainly due to polyethylene liner dissociation that can occur early or late. It appears to be a problem specific to the Pinnacle cup design rather than a feature of the similar third-generation acetabular components. The incidence is low, and it will require large national joint registries to collect data on liner dissociation to further address the question.

Conflict of interest

Dunedin Hospital receives an educational grant from DePuy Synthes to support an Arthroplasty Fellow.

For full disclosure statements refer to https://doi.org/10.1016/j.artd.2020.04.016.

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Chapter 8. Discussion

There will never be enough capacity for the potential demand for modern healthcare, which results in tensions between politicians, the Ministry of Health, DHB managers and surgeons. The political and ministry stated goals have been to increase the number of procedures, maintain equity of access across the country, give patients certainty whether they qualify for surgery or not, and to do the worst or most severe cases. The DHBs are expected to implement these goals despite their limited resource. They must avoid ESPI breaches, live within their budget and try to maintain their average intervention rate compared with the rest of the country. Surgeons want to do the best for the patient. If they believe that the benefits of surgery outweigh the risks they are likely to recommend surgery after appropriate discussion and informed consent. However, the Medical Council of New Zealand has stated that there is a duty on clinicians to responsibly use resources in an environment of healthcare limitation. Whilst able to advocate for patients, they must be a party to any rationing decisions. [1]

Demand

We have shown the increased demand for elective surgery, and hip and knee replacement in particular, is coupled with inadequate capacity. There is not equity of access to publicly funded surgery in NZ, with Southern DHB performing poorly. It appears that Otago and Southern DHB has been systematically disadvantaged under the PBFF and surgical services seem to have borne the brunt of this. There are increased costs with running two base hospitals within Southern DHB and the large geographical area covered. In acute specialties such as orthopaedic surgery there is a need for a sustainable service on both sites. The funding model is opaque and locally we appear to be disproportionately disadvantaged by the overseas tourist load, which is not directly funded. Our surgeons are probably less likely to offer surgery than in centres where rationing is less ingrained. We have demonstrated that, when capacity fails to meet demand in a system that does not have waiting lists, the thresholds for surgery rise. Patients end up being declined, re-referred and most eventually undergo surgery. In a system that is meant to be efficient, this process adds little value and a lot of waste.

Carpal Tunnel Decompression

We have been able to maintain good access to CTD through alternative models of care by using our day surgery unit, local anaesthetic and delegation to appropriate junior staff. Demand is driven by the increased incidence in elderly patients. Our results in the elderly, have been comparable or surpass international studies in younger age groups. We have the benefit of an excellent neurophysiological service which has greatly helped patient selection. By using a very basic DSU theatre/ procedure room we have freed up capacity in the main theatre suite for major cases.

Prevention

There remains little that can be done to prevent the burden of musculoskeletal disease and OA in particular. Our programme for DDH screening has helped reduce late presenting DDH and may have an effect on reducing acetabular dysplasia. It is a pragmatic solution with careful examination by experienced orthopaedic surgeons and selective use of ultrasound. We have found that ultrasound is particularly useful in monitoring patients with instability.

Population based interventions such as bisphosphonate treatment have reduced the incidence of fragility fractures. This indirectly helps elective surgery by reducing the acute demand. Obesity is likely to continue to rise and public health measures to control this are urgently needed. However, there will be a long lead-time before we see any effects of this and the demand will rise before any potential fall.

Joint Clinic and non-operative management

Similar programmes to our Joint Clinic operate in Sydney and Melbourne in Australia and Denmark. [2-4] In most instances their patients have had less severe disease and there has been ready access to surgery when indicated. In contrast, the Joint Clinic has provided mixed results. It has undoubtedly improved access and been useful as a triage tool though this was not the goal the Ministry of Health was interested in. It confirmed that patients with knee OA were more likely to benefit than those with hip OA. It was a little surprising to find the high proportion of patients with knee OA that were still being managed non-operatively at 5-7 years without a major decline in condition specific scores such as the Oxford Knee score. This justifies the increased use of good non-operative management including exercise therapy in patients with milder knee OA that can delay or even avoid surgery for a clinically relevant time. However, our paper comparing functional outcomes at 5 years does suggest that suitable patients are likely to be significantly better off with surgery that should not be delayed if non-operative treatment has failed.

Advocates for the introduction of widespread supervised exercise therapy as part of non-operative treatment are making claims on the basis of relatively small randomized controlled trials. [3-5] The Management of Osteoarthritis (MOA) group in Dunedin calculated the cost/ Quality Adjusted Life Year (QALY) of their physiotherapy programme as $26,000 (1x GDP) at 2 years. [5] This may be cost effective but many of these patients will eventually need TJR as well. To roll out supervised physiotherapy programs across countries such as Canada, Australia and as proposed in NZ at significant cost needs to be carefully compared with the long-term results of surgery. [7]

Despite the high initial cost, TJR gives a better return on investment. Both THR and TKR were highly cost-effective after 3 years using a threshold of $33,000 /QALY (0.5xGDP) falling to $6000/QALY for THR and $7500/QALY for TKA at 15 years using SF-6D. If EQ-5D is used the cost falls to $2700 and $3500 at 15 years. This is similar to the results calculated using the methodology of Jenkins et al from Edinburgh [6] where the lifetime QALYs gained after THR or TKR in patients with a preoperative OHS/OKS of 12 are 9.4 (THR) and 6.3 (TKR) and the cost/QALY $2222 and $3424 respectively.

Scoring tools

We have shown that scoring tools do work and correlate with condition specific scores. Using a prioritization nurse added little with surgeons generally scoring consistently. However, when there is a mismatch between demand and capacity there tends to be clustering at certain scores, score creep and little ability to discriminate around the threshold score.

The latest iteration of the orthopaedic surgical prioritization tool attempts to use a general score to cover all condition and includes a patient impact on life score. It is hoped that it will allow some comparison and access for patients with conditions other than hip and knee OA. Many of these patients would fail to qualify for surgery in the current climate. We are

seeing a lot of clinical over-ride used for carpal tunnel decompression because patients would not otherwise qualify. We believe that there should be separate thresholds for conditions such as carpal tunnel syndrome or Dupuytrens disease that can be effectively and efficiently treated in a day surgery facility allowing major inpatient cases to be performed in a fully equipped theatre. However, this has not been well received by the Ministry of Health who believe that the resources used for these procedures should be reallocated to areas that have higher need.

The new National Referral Prioritization Tool (NRPT) also includes the patient impact on life (IOL) score with the two scores correlating reasonably strongly. It has been of some use in our pilot but we found it to be labour intensive. Most surgeons believe that, while they are in the best position to triage these referrals, their time would be better-spent seeing patients instead of scoring and rejecting them. Its purpose was to restrict the number of referrals accepted to 50%, which it may have done, but this does not really mean success for those patients or the service.

The real value of national scoring tools will be in comparing threshold scores between specialties and DHBs to help inform resource allocations. However, this has not happened with the national orthopaedic surgical scoring tools to date. We know from talking to registrars and colleagues in other centres, and from published papers that there have been significant differences in access threshold across NZ. An anaesthetist from North Shore Hospital, writing in the latest edition of the ASMS publication 'The Specialist', was surprised to see an 88 year old lady coming to preadmission for a THR on crutches. [8] This has almost been a prerequisite for access in Otago for more than 10 years! The Ministry has been loath to release threshold scores to allow comparison between DHBs questioning the consistency of scoring within and between DHBs. It expects that DHBs should allocate their resources depending on local need. With limited budgets and a traditional split between the Planning & Funding and Provider arms of a DHB this has not happened and has been the source of great frustration.

Consequences of rationing

While rationing to a point is a reality, I believe it has gone too far when successful procedures such as THR and TKR surgery are restricted to patients with an OHS/OKS of around 10 points. This will have an impact on patients in that, although gains in scores and HRQoL are greater, the final outcome score is lower so patients lose potential QALYs both before and after surgery. Patients get re-referred, rescored and usually end up getting their surgery but in a more disabled state. It adds little value and encourages gaming by patients, GPs and surgeons. I do not think that the public sector should fund a TJR for anyone who is having some pain after 18 holes of golf despite finding, in our cost-effectiveness paper (5.7) that THR and TKR were highly cost-effective by 5 years even in patients with a preoperative OHS/OKS above 25. The argument from the UK that TKR is cost-effective in patients with preoperative OKS of 35-40 is, in my view, not relevant to the realities of public hospital practice in NZ. [9] Interestingly, it has been shown that patients with better scores and less radiographic change are more likely to be dissatisfied with the results of surgery. [10,11] Paradoxically our good results may be because of some degree of rationing.

Improving perioperative management

Our ERAS programme was successful. Buy-in by nursing and physiotherapy staff was key and was the biggest gain of the OPP. It is interesting to compare the modern results of ERAS with the best practice care pathways we used when I first returned as a consultant. However, it is hard to see how further significant gains can be achieved as we get down to a length of stay of 2-4 days. Day case THR is now being done in some centres but only in carefully selected patients. As our ERAS paper shows, over a third of our public patients are ASA grade 3 and 4, mean BMI is 30-32, the mean age is 68-70 years and pre-operative Oxford score is 10-12 points. Despite this almost all patients were discharged home rather than to step down facilities. We have continued to collect LOS data and by 2018 had reduced ALOS to 4.0 days for THR and 4.17 days for TKR. Unfortunately recent changes on the ward and a reduction in bed numbers have undone many of these improvements. Patients are rarely mobilized on the night of surgery and the LOS has recently increased again to 4.3 days for both THR and TKR.

Surgical outcomes

Our surgical results for hip replacement as demonstrated in the Morscher cup studies and the survivorship studies of the hybrid combination, match or surpass best international results. We have reported functional outcomes after hip and knee replacement that again match or surpass published results despite coming from a severely disabled public hospital population. Our poor outcomes after TKR are lower than that usually quoted. Several surgeons in Dunedin, including myself, have revision rates for THR and TKR significantly lower than the NZ average as reported by the NZ Joint Registry.[12] Our surgical site infection (SSI) rate after THR/TKR of 0.7% compares with the NZ average of 1.3% and is amongst the lowest in the country. [13] All this contributes to a lower revision burden, which frees up time for elective surgery.

What has been achieved in Otago

The original proposal for the Orthopaedic Patient Pathway programme (OPP) anticipated transformational change occurring due to all of the inter-connected projects, with the hope that efficiencies gained would thereby increase capacity. I had hoped that improved efficiency meant doing a lot more with a little additional investment. However it became clear that the goal was doing more with less, with no mechanism to return any of the gains to the orthopaedic department. This was both disappointing and disillusioning for the staff who had enthusiastically engaged in the programme.

The larger gains have come subsequently, when there has been investment. We commissioned a new theatre by upgrading an old plaster room adjacent to the orthopaedic theatre and now have access to an orthopaedic trauma theatre 6 days a week. This has had a limited effect on separating the acute and elective streams and reduced elective cancellations due to acute list pressure. However, the number of orthopaedic beds has fallen by a quarter from 54 to 40, so acute patients waiting for surgery cannot be admitted and now wait at home. Appointment of a new full-time arthroplasty surgeon and implementation of limited out-sourcing to the private sector has resulted in an increase in the number of primary hip and knee replacements from 358 in 2013/14 to 511 in 2018/19 as we predicted we needed. However, our standardised intervention rate (SIR) remains significantly below the NZ average for TKR as it has done for at least 10 years. During the

last 5 years we have under-provided on average 107 TKRs per year (28% shortfall) across Southern DHB compared with our expected share of the NZ total.

Other health care systems

Other public health care systems face similar challenges. Wherever we visit there are issues with wait lists of some form, lack of resourced beds due to acutes or out-lying patients (usually medical), a backlog of acute patients waiting for surgery leading to cancellations of elective lists and more patients being referred than can be seen by a specialist. Various strategies have been employed to try and improve access to elective surgery. Usually this is in the form of targets with bonuses or penalties for failing to comply. In the United Kingdom (UK), treatment centres for hip and knee replacement were developed with mixed results. Despite patients being healthier, outcomes on Oxford hip and knee score were a little worse and the risk of complications higher (OR 1.3) in patients managed at a treatment centre.[14] In the UK the 18-week target was introduced by which time patients had to be seen and treated. This was initially accompanied by significant increases in funding and capacity. Despite this, problems have continued with increasing demand for elective orthopaedic surgery outstripping capacity. Weekend, evening and extra lists are arranged at short notice, and high cost, to try to resolve the backlog and avoid financial penalties. Staff overtime then tends to lead to burn out and high turnover.

Canada has had similar problems and also introduced scoring systems. They were part of the approach used in Sakatchewan to improve wait list compliance. [15] However whole of system changes and out-sourcing were also used. Factors credited with success include management of the whole of care continuum, strong clinical leadership, and a culture of trust and innovation. Pomey in a review across several provinces of Canada noted strong funding, stakeholder engagement, physician involvement, human resource capacity, dedicated staffing, and financial incentives as factors for success. [16] In smaller centres wait lists in excess of 12 months for a routine (26 week) joint replacement remain. [Dusik personal communication].

In Australia, Walters et al reported on perceptions of snakes (barriers) and ladders (facilitators) and noted the main barrier was inadequate resources but highlighted a need for system change. [17] Ladders included pooled or generic wait lists and separation of acute and electives. Prioritization systems were perceived as 'wobbly ladders' of limited benefit. However, I believe that it is likely that scoring systems which are the norm in NZ will become more common overseas in public health care systems. It is important that there is transparency and consistency of scoring. Rather than condition specific tools, more generic HRQoL scores can be used to help compare the need between specialties, other conditions and alternative therapies.

The future in New Zealand

There is not equity of access across the country to elective orthopaedic surgery. Many factors may contribute to this including the age of patients, the relative size of the private sector and private insurance levels, under-provision in previous years, and the allocation of resources within a DHB. The funding model including funding for the care for overseas tourists probably needs some adjustments.

The demand will continue to rise as increasing numbers of patients get older and their expectations rise. This will need to be matched by an adequate number of staffed beds to

service the acute and elective load, more theatre time and more theatre staff. Obesity should not be regarded as acceptable from a health perspective and its management needs to be a priority in primary care. Culture and attitude changes are necessary which may require legislation. Exercise programmes such as those used in Joint Clinic should be available via primary care for patients with early stage hip and knee OA. This should have an effect on patients' perceptions that surgery is not the only solution but is reserved for failure of other treatments.

Prioritisation and rationing are necessary, but the bar is currently too high in Otago and some other DHBs. In these papers we have demonstrated clear evidence of inadequate capacity to match the demand. This is shown by the need to ration 50% of referrals, consistently declining 30% of wait-listed patients, the poor preoperative scores of patients who do qualify and wait times in excess of the 4 month target. The emphasis at DHB level should be on doing more work, rather than avoiding it in order to achieve ESPI compliance. This may require reallocation of resources from other areas within a DHB if there is no more funding from the Ministry of Health. The problems are not isolated to Dunedin and Southern DHB. As I predicted in 2016 in the conclusion to "*Rationing of hip and knee replacement: Effect on the severity of patient-reported symptoms and the demand for surgery in Otago"* they have become increasingly widespread across New Zealand as budgets fail to increase to match the demand.

Improving perioperative management and reducing complications remains important especially as patients become older and frailer. The ability to reduce length of stay is limited by this and the fact that stays are already short compared with historically. Making patients wait until they have deteriorated is counter-productive and is likely to increase LOS. Avoiding lengthy inpatient rehabilitation will have an impact at the hospital level and on orthopaedic bed availability if patients become stranded. Our surgical outcomes and revision burden have been very good but quality must not be sacrificed in the quest for efficiency. A significant concern is the expectation of a first class, error-free service by the public and the Health and Disability Commissioner despite economy class funding. It is not clear how long this expectation can be achieved without further investment.

There will never be enough money to run the health service and informed decisions need to be made which may not be popular. Hopefully national benchmarking, and outcomes data including cost-effectiveness, will lead to improved allocation of resources for high value interventions. Currently surgical rationing is being performed face to face with the patient. This interferes with the fundamental doctor-patient relationship, which is to try and help the patient without doing harm. While clinicians may be in the best position to judge, there also needs to be debate in the public arena about which services will be funded and to what level. In time this may be to only provide acute services. An honest open approach would be to inform the population so that they can take out private insurance or make other provision. However, this is likely to be politically unacceptable. Instead politicians of both sides promote the increasing numbers of procedures done and shorter wait times for those that qualify) which may give patients false hope.

The importance of these publications.

This can be judged either by the quality of journal in which they have been published or by the number of subsequent citations, although the two may not be related. 15 papers have been accepted or published in high-ranking peer-reviewed quartile 1 journals including the Bone and Joint Journal and Journal of Arthroplasty. 8 have been published in leading sub-speciality journals such as Foot Ankle International, Journal of Hand Surgery and Journal of Paediatric Orthopaedics. The issues pertinent mainly to New Zealand have been most appropriate to publish in either the Australian and New Zealand Journal of Surgery or NZ Medical Journal (9 articles). (Appendix 2)

As a result of these publications I have been asked to review articles in this field for leading international journals including the Bone and Joint Journal, BMJ Open, Arthritis Care and Research and Hip International.

The field of health service provision has not been particularly popular in the orthopaedic literature. Despite this papers such as our Care Pathway and ERAS papers, even though published in lower ranking journals, have been frequently cited. Seven papers have been cited on 20 or more occasions and 10 of the papers cited on more than 10 occasions. 13 of the publications contributing to this thesis have been published in the last 2 years so have not yet generated many citations. Several of the papers pertaining to New Zealand have achieved extensive media coverage including national TV and radio interviews, newspaper articles and editorials, and led to questions being asked in parliament. It is my hope that this work has helped to increase investment in orthopaedic surgery locally and nationally and will continue to do so.

Conclusion

In Otago we are currently under-servicing our population with respect to publicly funded elective orthopaedic surgery. Hip and knee replacement are established, highly successful interventions, not new innovations or fringe procedures of limited effectiveness. The burden for elective orthopaedic surgery will continue to grow rapidly with population growth, ageing and increasing rates of obesity. There are limited options to prevent this with efforts to reduce obesity having a lead-time of many years before we see any decline in demand. We feel that we are at the limit of rationing and it will become increasingly common in other centres in NZ and around the world.

In response to this increased demand, we have adopted new models of care, developed programmes to improve non-operative management, implemented scoring and prioritization systems, improved perioperative management and maintained excellent long term results that match or surpass national and international studies. The papers in this thesis have reported, audited and analysed the outcomes, consequences and results in a rigorous manner. The OPP programme did not achieve “transformational change” but we have achieved improvement. Efforts will continue to improve the whole system, which requires a collaborative approach between surgeons, non-medical staff, funders, management and politicians. The most significant underlying problem remains the lack of capacity compared with the increasing demand. This is due both to lack of infrastructure (operating theatres, physical beds) and staff (surgeons, theatre staff, ward nurses and allied health staff and staffed beds). There is a clear need for investment in the service which includes beds, theatre time, nursing staff and surgeons. We have done the groundwork and provided informed analysis on the scale of the problem, what works and what does not.

Now I believe it is time for funders, DHB management, the Ministry of Health and politicians to take note and play their part.

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Appendix 1 Papers making up this thesis.

Chapter 1

1.1 Quantifying the demand for hip and knee replacement in Otago, New Zealand. Gwynne-Jones D NZMJ 2013;126:1377 http://journal.nzma.org.nz/journal/126-1377/5710/

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Chapter 2

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Chapter 4

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Chapter 5

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Chapter 6

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Chapter 7

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Appendix 2 Journal and article metrics

Anaesthesia IF 5.879 4/31 Anaesthesia

Cardiopulmonary exercise testing in severe osteoarthritis: A crossover comparison of four exercise modalities. Roxburgh BH, Campbell HA, Cotter JD, Reymann U, Williams MJA, Gwynne-Jones DP, Thomas KN. Anaesthesia (2021) 76 (1):72-81. Doi 10.1111/anae.15162

Bone Joint J (Journal Bone & Joint Surgery [Br]) IF 4.301 6/76 orthopaedics

Bilateral uncemented total hip arthroplasty in osteopetrosis. DP Gwynne Jones, BF Hodgson & NA Hung J Bone Joint Surg 2003;86B:276-8 (19 citations)

The Morscher Press Fit acetabular component: A nine to 13 year review. Gwynne-Jones DP, Garneti N, Wainwright C, Matheson JA, King R. J Bone Joint Surg (Br) 2009;91-B:859-64 (18 citations)

Cemented or cementless acetabular fixation in combination with the Exeter Universal cemented stem: a survivorship analysis of 1086 hips at 12-18 years. Gwynne-Jones DP, Gray AR Bone Joint J (2020);102-B(4):414-422

J Arthroplasty IF 3.524 10/76 orthopaedics

The Joint Clinic: managing excess demand for hip and knee osteoarthritis referrals using a new Physiotherapy-led outpatient service. Gwynne Jones DP, Hutton LR, Stout KM, Abbott JH J Arthroplasty. 2018 Apr;33(4):983-987. doi: 10.1016/j.arth.2017.11.034. Epub 2017 Dec 1.(11 citations)

Outcomes and factors influencing response to an individualized multidisciplinary chronic disease management program for hip and knee osteoarthritis. Gwynne-Jones DP, Gray AR, Hutton LR, Stout KM, Abbott JH. J Arthroplasty (2018) Apr 16. pii: S0883-5403(18)30360-7. doi: 10.1016/j.arth.2018.04.011. [Epub ahead of print] (6 citations)

The outcomes of non-operative management of patients with hip and knee osteoarthritis triaged to a physiotherapy-led clinic at minimum 5-year follow-up and factors associated with progression to surgery. Gwynne-Jones JH, Wilson R, Wong J, Abbott JH, Gwynne-Jones DP [published online ahead of print, 2020 Feb 7]. J Arthroplasty. 2020;S0883-5403(20)30123-6. doi:10.1016/j.arth.2020.01.086 (3 citations)

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The Morscher Press-Fit Acetabular Component: An Independent Long-Term Review at 18-22 Years. Gwynne-Jones DP, Lash HWR, James AW, Iosua EE, Matheson JA. J Arthroplasty 2017;32:2444-2449 (2 citations)

Hybrid Fixation for Total Hip Arthroplasty Showed Improved Survival Over Cemented and Uncemented Fixation: A Single-Center Survival Analysis of 2156 Hips at 12-18 Years. Fowler AK, Gray AR, Gwynne-Jones DP. J Arthroplasty. 2019;34(11):2711–2717. doi:10.1016/j.arth.2019.06.031 (3 citations)

The effect of sagittal laxity on function following posterior cruciate retaining total knee replacement. DP Gwynne Jones, C Locke, J Pennington & JC Theis JC. Arthroplasty 2006; 21(5):719-723 (36 citations)

Rationing for Total Hip and Knee Arthroplasty Using the New Zealand Orthopaedic Association Score: Effectiveness and Comparison With Patient-Reported Scores. Gwynne-Jones DP, Iosua EE, Stout KM. J Arthroplasty. 2016 May;31(5):957-62. doi: 10.1016/j.arth.2015.11.022. Epub 2015 Nov 26 (17 citations)

Total Hip and Knee Arthroplasties Are Highly Cost-Effective Procedures: The Importance of Duration of Follow-Up. Ross A. Wilson, David P. Gwynne-Jones, Trudy A. Sullivan , J. Haxby Abbott. J Arthroplasty (2021) https://doi.org/10.1016/j.arth.2021.01.038 (epub ahead of print)

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BMC Musculoskeletal diseases IF 2.38
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Foot Ankle International IF 2.341 29/76 orthopaedic
Acute Achilles Tendon Rupture: Epidemiology and outcomes of 363 patients with operative or non-operative treatment using an identical functional bracing protocol. Gwynne-Jones DP, Sims M., Handcock D. Foot Ankle International 2011 32:4; 337-343 (60 citations)

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J Hand Surgery (Am) IF 2.09 32/76 orthopaedics

Incidence of Carpal Tunnel Syndrome Requiring Surgical Decompression: A 10.5-Year Review of 2,309 Patients. English JH, Gwynne-Jones DP.J Hand Surg Am. 2015 Dec;40(12):2427-34. doi: 10.1016/j.jhsa.2015.07.029. Epub 2015 Oct 10 (17 citations)

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The National Referral Prioritization Tool For First Specialist Assessment : Results of the Pilot Study in Orthopaedic Surgery. Gwynne-Jones DP, Wilson R, McEwan C ANZ J Surg (2020)90 (9):1738-1742 doi 10.1111/ans.16002

Arthroplasty Today IF 1.09

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The relationship between preoperative Oxford hip and knee score and change in health-related quality of life following total hip and total knee arthroplasty: Can it help inform rationing decisions? Gwynne-Jones DP, Wilson R, Sullivan T, Abbott JH Arthroplasty Today (2020) 6(3):585-589e1 doi 10.1016/j.artd.2020.04.009 (1 citation)

Acetabular liner dissociation: A comparative study of two contemporary uncemented acetabular components. Gwynne-Jones DP, Memon AR Arthroplasty Today (2020) 6:354-359. doi 1016/j.artd.2020.04.016

J Orthopaedic Surgery (Hong Kong) IF 0.957

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NZ Medical Journal IF 0.452

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The projected burden of knee osteoarthritis in New Zealand: healthcare expenditure and total joint provision. Gwynne Jones DP, Hooper G *New Zealand Medical Journal*, *132*(1506), 101-103. Retrieved from https://www.nzma.org.nz/journal. [Letter].

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